

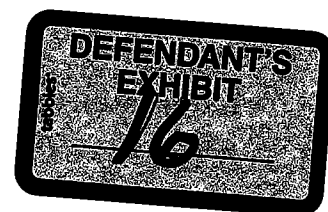
EXHIBIT 16

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
MDL No. 1968

IN RE:
DIGITEK PRODUCT
LIABILITY LITIGATION

VIDEOTAPED
DEPOSITION OF:
MARK G. KENNY
VOLUME I

TRANSCRIPT of the stenographic notes of
the proceedings in the above-entitled matter, as
taken by and before CAROL ANN SHEPARD, a Certified
Court Reporter of the State of New Jersey, held at
the MARRIOTT NEWARK AIRPORT HOTEL, 1 Hotel Road,
Newark, New Jersey, on Tuesday, June 29, 2010,
commencing at 8:30 in the forenoon.



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24

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1 THE VIDEOGRAPHER: Good morning. We
2 are on the record at 8:41 A.M., June 29, 2010. This
3 is the videotaped deposition of Mr. Mark G. Kenny in
4 the matter of In Re: Digitek Product Liability
5 Litigation, in the United States District Court for
6 the Southern District of New York, MLP Case No.
7 2:09-CV-121.

8 This deposition is being held at the
9 Marriott at Newark Airport Hotel, located at 1 Hotel
10 Road in Newark, New Jersey.

11 I am the videographer. My name is Adam
12 DiCola of Rennillo Reporting. Our court reporter is
13 Carol Ann Shepard, also with Rennillo Court
14 Reporting.

15 Will counsel please state their
16 appearances for the record.

17 MS. CARTER: Meghan Carter, Motley
18 Rice, for the Plaintiffs.

19 MR. MILLER: Peter Miller from The
20 Miller Firm for Plaintiffs.

21 MR. MORIARTY: Matt Moriarty from
22 Tucker Ellis for the Actavis Defendants.

23 MR. ANDERTON: Michael Anderton from
24 Tucker, Ellis & West, also for the Actavis
25 Defendants.

1 MR. KAPLAN: Harvey Kaplan, Shook,
2 Hardy & Bacon for Mylan.

3 MR. MORIARTY: Just so the record is
4 clear, this is the Southern District of West
5 Virginia that this litigation is in, not New York.

6 Ready?

7 M A R K G. K E N N Y, 2 SpyGlass Court,
8 Annandale, New Jersey, having been duly sworn,
9 testifies as follows:

10 EXAMINATION BY MR. MORIARTY:

11 Q. Tell us your full name, please.

12 A. My name is Mark George Kenny.

13 Q. All right. And, Mr. Kenny, have you
14 ever had your deposition taken before?

15 A. Never.

16 Q. First time. Okay.

17 I'm sure that either Mr. Miller or
18 Ms. Carter has told you that I'm going to ask you a
19 lot of questions today.

20 Okay?

21 They've done that, I assume?

22 A. Correct.

23 Q. And you know we probably will be here
24 all day. Is that right? And even then we may not
25 finish.

1 Do you know that?

2 A. Correct.

3 Q. If you don't know the answer to my
4 question, please tell me that you don't know.

5 All right?

6 A. Yes, sir.

7 Q. If you don't understand my question,
8 please tell me that you don't understand me.

9 Okay?

10 A. Sure.

11 Q. If you need to look at a document,
12 including your report, your resume or anything else,
13 in order to answer my question, please do that.

14 Okay?

15 A. Yes, sir.

16 Q. I don't want you to guess.

17 You're going to have to keep your voice
18 up loud because the court reporter has to hear you.

19 All right?

20 A. Okay.

21 Q. And if you say uh-huh or uh-uh, I will
22 say is that a yes or is that a no --

23 A. Right.

24 Q. -- because she needs to understand
25 these things in plain English.

1 Okay?

2 A. Surely.

3 Q. Now, at some point, we will mark your
4 resume as Exhibit 47. But that was made Appendix A
5 to your report in this case.

6 Is --

7 A. Correct.

8 Q. -- that right?

9 And I notice that you live on SpyGlass
10 Court.

11 Is that right?

12 A. That is correct.

13 Q. And the name of your consulting company
14 is the SpyGlass Group.

15 Is that right?

16 A. That is correct.

17 Q. How many employees does SpyGlass Group
18 have?

19 A. We have no employees.

20 Q. You are not even employed by SpyGlass?

21 A. Well, I'm an employee under a sub --
22 Subchapter S, yes, and so is my wife.

23 Q. And you are the only employees?

24 A. That is it.

25 Q. Do you have any agreements with other

1 people who are independent contractors and do
2 consulting work for you?

3 A. We have agreements when there is a
4 project.

5 Q. All right. So on the -- on the Digitek
6 project, how many people reviewed documents and
7 worked to help you prepare this report?

8 A. There were two additional people, one
9 Dr. Sal Romano, and my wife, who proofed it.

10 MR. KAPLAN: Dr. who?

11 THE WITNESS: My wife.

12 MR. KAPLAN: No, no. Dr. --

13 THE WITNESS: Dr. Sal Romano.

14 Q. What's your wife's name?

15 A. Denise.

16 Q. Denise Kenny?

17 A. That's correct.

18 Q. Did she do any technical input?

19 A. None whatsoever.

20 Q. And who is Sal Romano?

21 A. Sal Romano is also a consultant. He is
22 a core member of our consulting group and a former
23 quality assurance professional -- when I say former,
24 I mean working full time for a large company,
25 Johnson & Johnson -- who has done consulting for

1 over 10 years.

2 Q. All right. So I assume that when
3 SpyGlass -- when you or SpyGlass Group are asked to
4 do, say, a consulting project for a pharmaceutical
5 company --

6 A. Correct.

7 Q. -- if you can't staff that by yourself,
8 you reach out to people with whom you have previous
9 relationships and bring them in as consultants on
10 that project.

11 Is that right?

12 A. That's correct.

13 Q. Okay. How old are you?

14 A. I'm 61 years old.

15 Q. Appendix B to your report, which we
16 will also have as an exhibit, is -- is referred to
17 as "References."

18 Is that correct?

19 A. That is correct.

20 Q. And on here are 60 listings.

21 Is that right?

22 A. That is correct.

23 Q. Have you reviewed anything else besides
24 these 60 listings since you drafted the report?

25 A. Since I drafted the report, yes.

1 Q. All right. Can you tell me what else
2 you reviewed since drafting this?

3 A. I looked at some Mylan depositions.
4 There was nothing I felt substantive.

5 Q. Whose depositions?

6 A. I don't recall the name.

7 Q. Well, there was a -- Chuck Koon was
8 deposited.

9 Did you look at his deposition?

10 A. I briefly went through it.

11 Q. Did you look at Lianna Radtke's
12 deposition?

13 A. No, I did not.

14 Q. I think there was a -- Susie Wolf was
15 deposited.

16 Did you look at her deposition?

17 A. I did not.

18 Q. Anything else that you can recall
19 reviewing since you drafted your report?

20 A. No.

21 Q. Did you leave J&J in 2004?

22 A. Yes, I did.

23 Q. Why?

24 A. I was offered, as was everybody in the
25 United States, an early retirement package. I had

1 the option of leaving or I had the option of
2 staying.

3 Q. And you took the option of the early
4 retirement package?

5 A. Yes. Indeed. That's correct.

6 Q. All right. Did you meet with and talk
7 with Mr. Miller either last night or this morning --

8 A. No.

9 Q. -- to talk about any last-minute
10 developments before your deposition?

11 A. Nothing.

12 Q. Have you heard anything from anyone
13 amongst the plaintiffs' lawyers about what happened
14 during Mr. Farley's deposition yesterday?

15 A. No. Nothing.

16 Q. So what -- give me a general idea of
17 what consulting projects you work on now under this
18 banner of the SpyGlass Group.

19 A. Okay. I would say half of the projects
20 that I work on are auditing, auditing of medical
21 device, drug companies. And that would be for GMP
22 purposes, also for ISO Regulation 1345:2003.

23 The other projects are really
24 assistance in risk determinations, establishment of
25 quality systems, establishment of quality plans,

1 establishment of master validation plans, reasonably
2 high-level documents that would be submitted to the
3 management board or management level of a company.

4 Q. Do you ever help companies remediate
5 483s or warning letters?

6 A. As a consultant?

7 Q. Yes.

8 A. No.

9 Q. How much of your consulting work is
10 spent on solid oral dose?

11 A. You mean over the six-year period?

12 Q. Yes.

13 A. I would say within the last two years,
14 30 percent.

15 Q. And how much of it is device work?

16 A. It would be over half. 60 percent.

17 Q. In the six years of SpyGlass Group
18 consulting, have you done any 483 or warning letter
19 remediation work?

20 A. I would have to answer that yes.

21 Q. When you worked for J&J in your various
22 capacities over the years, were part of your duties
23 to look at 483s and warning letters --

24 A. Of course.

25 Q. -- and help the company remediate them?

1 A. Yes.

2 Q. In the process of doing that, as an
3 example, if you got a 483 that had to do with a
4 manufacturing issue, would it be part of your job to
5 look at batch records?

6 A. It could be, but probably would not be.

7 Q. Why?

8 A. Because I would not get involved at
9 that level. I would get involved more at a
10 strategic level, determining whether the action
11 plans are comprehensive, rather than going through
12 the detail of reading batch records that normally
13 would be done by somebody else.

14 Q. But as part of the project --

15 A. Yeah. You're talking -- are you
16 referring to a 483 project, or are you referring to
17 in general a project?

18 Q. A 483 or warning letter remediation.

19 A. No. I -- I take that back. Yes, I
20 would.

21 Q. You would personally look at them or --

22 A. Yes.

23 Q. -- you would supervise somebody?

24 A. No. I would do it myself.

25 Q. All right.

1 A. But would not -- I would not -- that is
2 not a major portion of what I do.

3 Q. But --

4 A. For -- for 483 remediations.

5 Q. Sure.

6 A. I do a high -- an extraordinary number
7 of batch reviews, capital reviews and the like as
8 part of my consulting practice over the last six
9 years.

10 Q. So, for example, if somebody is looking
11 for a way to improve a manufacturing process, for
12 example, looking at batch records regarding that
13 process is something you would do?

14 A. That's correct.

15 Q. And if there was some question about
16 whether a process was validated or robust or staying
17 in validated control, looking at the batch records
18 over time would be one of the things that would be
19 important to do?

20 A. That's correct.

21 And they would rely on me to be able to
22 make that determination.

23 Q. All right. In your years at J&J or as
24 a consultant, have you ever been involved in the
25 manufacture, QA or QC of a Digoxin product?

1 A. Never.

2 Q. Now, over the years, in your work, have
3 you come to appreciate the difference between
4 possibility and probability?

5 A. I would think I do.

6 Q. All right. So probability, for
7 example, is generally defined as more likely than
8 not.

9 Would you agree with that?

10 A. I would say that's reasonably fair.

11 Q. And possibility is more in the realm of
12 speculation.

13 Is --

14 A. Correct.

15 Q. -- that true?

16 So that can -- can happen, might
17 happen, that's possibility and speculation; right?

18 A. I would have to think about the terms,
19 but that -- that, perhaps, is a way of explaining
20 it. I would not use those terms precisely.

21 I would determine risk levels.

22 Q. Now, your report in this case, we're
23 going to ultimately mark as Exhibit 48, but I would
24 like you to take a look at page 23 of that.

25 A. Yes, sir.

1 Q. Do you have that in front of you?

2 A. Yes, I do.

3 Q. And on this page, there is a section
4 called "Quality and Quality Systems SpyGlass Group
5 Summary."

6 Do you see that?

7 A. Yes, I do.

8 Q. And essentially, after the first 22
9 pages of your analysis, this is the one-sentence
10 essence of your opinion.

11 Is that right?

12 A. I suppose you could put it that way.

13 Q. Okay. And it says that: "It is my
14 opinion, to a reasonable degree of certainty, that
15 Actavis failed to establish reliable and GMP
16 compliance systems and procedures, resulting in the
17 release of adulterated product from at least the
18 period of 2004 to 2008."

19 A. Correct.

20 Q. Right? Okay.

21 And among the things that you relied on
22 in this Appendix B are a number of FDA documents,
23 like 483s and warning letters; correct?

24 A. That is correct.

25 Q. And what are known as EIRs or

1 establishment inspection reports?

2 A. That is correct.

3 Q. I don't see anywhere on Exhibit B
4 references to batch numbers, other than
5 Batch 70924 A.

6 Did you review any other batch records?

7 A. Yes, I did. Perhaps two more.

8 Q. Which ones?

9 A. I don't recall the batch numbers.

10 Q. All right. Do you -- do you know how
11 many recalled batches there were in the Digitek
12 recall of April of 2008?

13 A. No, I don't.

14 Q. There were 151 or 152 of them.

15 Is what you're telling me now that you
16 may have reviewed as many as just three of those?

17 A. Batch records, yes. That's all I -- I
18 had available to me.

19 Q. Do you know when batches were
20 manufactured, when batches were first manufactured
21 that were part of the recall?

22 A. I would assume, and I think it's a safe
23 bet, that the batches would have been manufactured
24 within the expiration date that it was in the field.

25 In other words, all batches would have

1 been recalled that were still within the expiry
2 date.

3 Q. Do you know how long Digitek's
4 expiration date is?

5 A. For what product?

6 Q. Digitek.

7 A. Oh, for Digitek? No, I don't.

8 Q. Did you review any method operating
9 instructions --

10 A. Yes.

11 Q. -- from Actavis?

12 A. Yes, I did.

13 Q. How many of them?

14 A. Probably a dozen plus.

15 Q. Are they listed in Exhibit B?

16 A. No.

17 Q. Appendix B?

18 A. No. I had no reference to them.

19 Q. What do you mean you had no reference
20 to them?

21 A. In other words, I had no observation to
22 those particular documents.

23 Q. What does that mean?

24 A. Could you restate your question?

25 Q. What do you mean "observation"?

1 Are you talking about in the regulatory
2 sense of observation being --

3 A. Could you repeat the first question,
4 please?

5 Q. I'm going to ask you a new question.

6 MR. MILLER: Well, I think he wants to
7 make sure he understands the line of questioning.

8 You asked him the first question. If
9 you reask the first question, then perhaps he can
10 phrase it.

11 Right -- right now, he's confused about
12 what the line of questioning is.

13 Q. Well, there are no MOIs listed in
14 Appendix B. You said it's because you had no
15 observations about it.

16 A. I read certain documents. And I had no
17 comment on those.

18 Q. Okay. So, for example, if MOI 145 has
19 to do with QC testing of Digitek, you didn't find
20 anything deficient, for lack of a better term, in
21 MOI 145.

22 MR. MILLER: Object. I'll object. If
23 you'd let -- allow me, I'll object; and when I'm
24 done, then you can finish.

25 I'm sorry. Excuse me. But objection.

1 Misstates previous testimony.

2 It's okay to answer.

3 A. Okay. If your question -- if you're
4 asking me did I look at documents and see
5 deficiencies in the documents, the answer to that
6 would be yes, I did see deficiencies in documents
7 that do not appear in here.

8 Q. That's not what I'm asking you.

9 Did you review MOI 145?

10 A. I don't recall.

11 Q. Well, if you found a deficiency in a
12 method operating instruction regarding a key
13 manufacturing or testing process for Digitek, is it
14 likely that you would have put it in your report?

15 A. If I -- if it -- it was significant and
16 if I saw it, I may have put it in the report, if I
17 felt it was important.

18 Q. Did you understand -- well, first of
19 all, have you ever done litigation consulting before
20 this case?

21 A. No, I have not.

22 Q. Did either Mr. Miller or anybody from
23 Motley Rice let you know that the purpose of this
24 report was to put us on notice of what your opinions
25 were?

1 A. Yes.

2 Q. And what documents you relied on to
3 reach those opinions?

4 A. Right. And I provided those documents
5 in the box.

6 Q. I understand that.
7 And you also listed 60 items that you
8 reviewed.

9 A. Correct.

10 Q. So let me get back and make sure I
11 understand this.

12 MOI 145 has to do with QC testing for
13 Digitek. I want you to assume that.

14 A. Okay.

15 Q. If you found that the QC testing
16 process for Digitek was deficient in some way,
17 technically or by some GMP standard, and you
18 reviewed the document, is it likely you would have
19 commented on it in your expert's report?

20 A. Okay. I think it's important to
21 understand that I am not an analytical chemist.

22 My experience is -- education
23 experience is as an engineer, both mechanical
24 engineer and a biomedical engineer in graduate
25 school.

1 When I review laboratory records, I
2 look at them from a compliance standpoint, not a
3 technical standpoint.

4 So I would review them, making sure
5 that there would be certain content in there in
6 terms of whether they appeared complete.

7 I would also be looking at -- if it was
8 a test method, which I think you are referring to, I
9 would ask whether there was a method validation
10 study in order to ascertain whether the test method
11 is valid.

12 That is the question that I would ask.
13 And that would, to me, be among the most important
14 questions.

15 Q. Okay. So if the technical aspects of
16 MOI 145 for the lab testing of Digitek, would you
17 feel more comfortable deferring to a quality control
18 chemist for opinions on whether that MOI was
19 consistent with the United States Pharmacopeia?

20 A. I would ask the research person that,
21 not the quality control person.

22 The research person is the person who
23 understands the regulations, is responsible for
24 developing the procedure.

25 The quality control person is not

1 responsible for the technical content of that
2 document. The quality control person is responsible
3 for executing that document, is responsible for
4 being part of the method transfer, is not even part
5 of the method validation study.

6 That person is an expert in performing
7 reproducible studies and getting accurate results.

8 Q. But certainly the quality control
9 chemist is the person who actually has to be
10 performing the study --

11 A. That's correct.

12 Q. -- to get the results that are
13 documented in batch records; right?

14 A. That's correct. The basis of the
15 numbers that are in specification. They would not
16 necessarily understand why those numbers were
17 selected.

18 Q. Okay. These 483s that we have been
19 talking about are regulatory documents sent to a
20 company by the FDA; correct?

21 A. That is correct.

22 Q. And a warning letter is also a
23 regulatory document sent to a company by the FDA?

24 A. That's correct.

25 Q. I'm handing you what's been marked as

1 Exhibit 63.

2 (Exhibit 63, Chapter 4, Advisory
3 Actions, was marked for identification.)

4 Q. This is Exhibit 64.

5 (Exhibit 64, Chapter 10, Other
6 Procedures, was marked for identification.)

7 Q. Have you ever seen these documents
8 before?

9 A. I have not.

10 Q. These are from the Regulatory
11 Procedures Manual of the FDA.

12 Have you ever seen any parts of the
13 Regulatory Procedures Manual for the FDA?

14 A. I have not.

15 Q. First, I'd like you to take a look at
16 Exhibit 63.

17 A. Okay.

18 Q. First page, it's entitled "Warning
19 Letters"; is it not?

20 A. Yes, it is.

21 Q. And one, two, three, four lines down it
22 says: "Warning letters are issued to achieve
23 voluntary compliance and to establish prior notice."

24 Do you agree with that?

25 A. Yes.

1 Q. Go to the next page, please, which is
2 4-2, the fourth full paragraph.

3 It says: "A warning letter is informal
4 and advisory."

5 Do you agree with that?

6 A. Do I agree with that from a practical
7 standpoint?

8 Q. Well, do you -- sure.

9 A. All right. Let's put it this way --

10 Q. Do you agree or disagree with the FDA's
11 own Regulatory Procedures Manual?

12 A. May I ask you a question?

13 Q. Actually, you can't. I ask questions.

14 A. All right. I will state what I think.
15 From a --

16 MR. KAPLAN: Just answer the question,
17 because I'm going to move to strike any answer
18 that's not responsive.

19 Please answer just the question that's
20 asked. No statements, no speeches.

21 MR. MILLER: Well, I think his
22 statement is in response to the question.

23 MR. MORIARTY: Well, let him make his
24 statement, and I'll deal with it. I haven't heard
25 his statement.

1 MR. MILLER: That's what we're trying
2 to do, Matt. Let's do it.

3 Go ahead, make your statement.

4 A. Could you ask the question?

5 Q. Yes. At page 4-2 of the FDA's
6 Regulatory Procedures Manual, it says: "A warning
7 letter is informal and advisory."

8 Do you agree with that statement?

9 MR. MILLER: And I'm going to object to
10 reading one sentence out of a document he's never
11 seen before and asking him if he agrees with it.

12 I think he ought to take the time to
13 read at least the whole paragraph and put it in
14 context.

15 Q. It's a three-sentence paragraph. Go
16 ahead and read it.

17 A. From an FDA standpoint, I agree with
18 this.

19 Q. The next sentence says: "It
20 communicates the agency's position on a matter, but
21 does not commit FDA to taking enforcement action."

22 Do you agree with that?

23 A. Yes, I do.

24 Q. The next sentence says: "For these
25 reasons, FDA does not consider warning letters to be

1 final agency action on which it can be sued."

2 Do you agree with that?

3 A. I don't have the basis to disagree. I
4 don't know what the basis for suit -- for forming a
5 suit would be.

6 Q. Do you know what "final agency action"
7 is?

8 A. No. I don't know the term.

9 Q. Now, are warning letters considered the
10 second step in this sort of note -- written
11 notification chain?

12 A. From a business standpoint, yes.

13 Q. The first step would be the 483.
14 Is that right?

15 A. Correct.

16 Q. And a 483 is also informal and
17 advisory.

18 Is it not?

19 A. I don't perceive it as that.

20 Q. Well --

21 A. I perceive -- I perceive it as a
22 company put on warning that you have some
23 potentially very significant issues, or it would not
24 have been in the 483, and that you're expected to
25 understand those issues, investigate those issues,

1 determine whether they represent systemic issues,
2 and then put in corrective action plans that are
3 appropriate with the risk determination that you've
4 made as a result of your investigations.

5 Q. Do you have any opinion about whether
6 the FDA considers 483s to be final agency action?

7 A. I don't have the experience to answer
8 that question.

9 Q. All right. Have you ever worked for
10 the FDA?

11 A. I have not worked for the FDA.
12 I worked with the FDA.

13 Q. Well, I assume what you mean by that is
14 when you were at J&J, sometimes you had to interact
15 with FDA regarding recalls or investigations or
16 something else; correct?

17 A. I would not put it that way. So if you
18 want me to put it my way --

19 Q. How did you interact with FDA?

20 A. I interacted with the FDA during an
21 inspection by the FDA if I determined in the
22 company, within the company I work for, that I would
23 be additive to the process.

24 I worked with the FDA on, for example,
25 a home HIV test, which was basically the first --

1 first concept of an HIV test that the consumer would
2 participate in the testing itself.

3 The regulations really didn't exist
4 that were specific to that, so the FDA had to -- had
5 to try to understand the technology, had to try to
6 interpret the GMP regulations.

7 And we assisted the FDA in doing that.
8 And they assisted us in helping establish
9 development validation. Because, again, this --
10 this was a novel product.

11 So I have worked directly with the FDA
12 on items like that.

13 Q. Essentially, your whole working career
14 from 1974 to 2004 was with different J&J companies.

15 Is that right?

16 A. That's correct.

17 Q. All right. In your years at J&J, was
18 any part of J&J under a consent decree?

19 A. To my knowledge, no.

20 Q. To the best of your knowledge, while
21 you were at J&J over those years, were any products
22 ever seized by the FDA?

23 A. Not to my knowledge.

24 Q. Were any of the companies that you
25 worked for at J&J ever given Form 483s by the FDA?

1 A. Yes.

2 Q. Were any companies that you worked for
3 at J&J given warning letters by the FDA?

4 A. Yes.

5 Q. When you were with J&J, did J&J have
6 product recalls?

7 A. Did J&J? You mean the \$60 billion
8 company, of course?

9 Q. Did any of the business units for which
10 you worked have recalls?

11 A. I only had one recall in my entire
12 career, which had nothing to do with compliance.

13 Q. What did it have to do with?

14 A. It had to do with two items. I'm
15 sorry. Had to do with one item. And it's
16 reasonably complex. Would you like me to go through
17 the description of what happened?

18 Q. No. I'd like the Reader's Digest,
19 simple version.

20 A. I will do my very best.

21 We sold a product, a home HIV test,
22 which had a mailer. The customer participated in
23 the test by pricking their finger and putting three
24 blood droppings on a sample card. It was a paper
25 card, the same as -- anyway, it was a paper card

1 designed for that purpose, used by the FDA for the
2 last 50 years.

3 They would then send -- mail that to
4 the -- to the test center, which was under contract
5 with us. And they would actually do the testing of
6 that and determine whether or not it was positive or
7 negative, the results.

8 Okay? Now, the mailer that Johnson &
9 Johnson initially used was not a -- a -- a
10 Fed Ex-type mailer. It was a normal mailer that
11 took three days to arrive at the lab.

12 The competition, six months after we
13 launched the product, put in next-day mailing
14 service.

15 Unbeknownst to everybody in the company
16 that I was aware of but sales, they decided to
17 develop mailers to expedite this.

18 So they went into the field, pulled out
19 the mailer for the three-day, you know, cycle and
20 put in the mailer for the one-day cycle.

21 Okay. I was -- I was not aware of it.
22 I would not have authorized it, but it happened. It
23 sounds innocent.

24 The product was kept behind the counter
25 in most instances. It was almost a \$40 product.

1 They were afraid -- pharmacists were afraid that the
2 product would be stolen.

3 The salesmen, I was told, were given
4 instructions to physically place the mailer on the
5 product.

6 So when they went into the pharmacy,
7 sometimes they did it, apparently. Sometimes they
8 did not. The pharmacy frequently would say -- not
9 frequently; we didn't have that many examples -- but
10 would say, I will do it for you because it is behind
11 the counter. Don't worry about it. Leave the
12 mailers. How many products do I have? Three.
13 Leave three mailers.

14 The pharmacists made an error, in that
15 when the competition came out, it was kind of like
16 Walmart. They made a product that looked identical
17 in color, identical in shape, so that when the
18 pharmacist went to put the mailer onto the -- onto
19 Confide, which was the product, they -- and I don't
20 know if it was six instances, eight instances -- put
21 them on the competitive product.

22 Q. Okay. Let me stop --

23 A. Can I finish the concept?

24 Q. No. Let me just stop you for a second.

25 I think I see where this story is going.

1 I take it that this recall was not
2 because of the quality or integrity of the HIV
3 testing itself?

4 A. That's correct. As a matter of fact,
5 we were above, if you will, the gold standard.

6 Q. Okay. The recall was for regulatory
7 reasons related to FDA being involved in labeling
8 and other things post --

9 A. No. No. That's not correct.

10 Q. -- unrelated to the test itself?

11 A. No. It's related to the test. The
12 samples went to the wrong lab. They went to the
13 competition.

14 Q. No. That's not what I'm asking.
15 The quality or integrity of the HIV
16 test itself was not the reason for the recall?

17 A. The integrity -- in other words, if the
18 samples arrived to the correct lab, and those
19 samples were -- see, we would receive competitive
20 samples.

21 Could the integrity of that test be
22 compromised? It is conceivable, because we don't
23 know how their paper was made. We don't know their
24 test methodology. We only know what we did. They
25 had the wrong competitive information.

1 So is it conceivable? Yes. Is it --
2 you're talking about probabilities. Probability
3 would be low.

4 Q. Okay.

5 A. But there is a probability that it
6 would not be tested. So you would have somebody who
7 had -- who had -- would not have gotten the results.

8 Q. Okay. Among the things that you
9 reviewed, in Appendix B, Item Number 7 is a website?

10 A. Item Number 7 is a website. Correct.

11 Q. Now, is that a part of the FDA's
12 website?

13 A. No. No, it is not.

14 Q. So this is some --

15 A. Another consulting firm's.

16 Q. Learning Plus, Inc.?

17 A. I don't recall the exact -- I'd have to
18 pull the website up.

19 Q. But this is their description of what
20 the warning letter is and later what GMPs are;
21 correct?

22 A. No. No.

23 Q. Well, I --

24 A. That is --

25 Q. -- printed --

1 A. That is specific to the reference.

2 Q. I printed your Reference B. Okay?

3 There is the definition of a warning letter.

4 A. Right.

5 Q. There is -- from Learning Plus, Inc.

6 Do you see that?

7 A. Yes.

8 Q. There's about this site.

9 Do you see that?

10 A. Yes.

11 Q. There's their definition of GMPs.

12 Do you see that?

13 A. Yes.

14 Q. Okay. This is not an FDA website?

15 A. That is correct.

16 Q. What I would call the official
17 definition of what a warning letter is, according to
18 the FDA; correct?

19 A. That is correct.

20 Q. Do you have any opinion on whether or
21 not an establishment inspection report constitutes
22 final agency action of the FDA?

23 A. Yes. It does not constitute final
24 action.

25 Q. All right. Tab 9 in your Appendix B is

1 Plaintiffs' Exhibit 147. It is an E-mail about a
2 483.

3 Do you have that?

4 A. Do I have it in my -- yes, I do. Would
5 you like me to try to pull it?

6 Q. Or you can just use mine.

7 A. If it's correct.

8 Q. What do you mean if it's correct? You
9 think I'm BSing you?

10 MR. MILLER: Objection. That's not
11 what he was saying.

12 MR. MORIARTY: I don't know what he was
13 saying.

14 Q. First of all, the first page of
15 Exhibit 147 is an E-mail; correct?

16 A. That is correct.

17 Q. The next page is a 483 from the FDA to
18 Actavis Totowa from the inspection of March 18
19 through May 20, 2008.

20 Do you see that?

21 A. Yes. This is -- 147 continued into the
22 483?

23 Q. It's one exhibit.

24 A. Is this a new exhibit?

25 Q. It's one exhibit.

1 A. Okay.

2 Q. It is a plaintiffs' exhibit.

3 A. Okay.

4 Q. Do you see this Observation 2?

5 A. Yes, I do.

6 Q. Underneath Observation 2, there is a
7 statement that says: "Drug products failing to meet
8 established specifications and quality control
9 criteria are not rejected."

10 Do you see that?

11 A. Yes, I do.

12 Q. In Chuck Koon's deposition, he said
13 that this is essentially the Turbo software
14 restatement of the language from an FDA regulation.

15 Do you agree with that?

16 A. Oh, I don't know.

17 Q. Okay. And then what Chuck Koon said is
18 that under specifically is the example that an FDA
19 inspector gives based on their inspection.

20 Do you know anything about that?

21 A. No. I -- in other words, if you're
22 stating that this is the highlight, and this
23 substantiates that highlight, this is -- this is
24 the, you know, front page heading, and then they go
25 into specifics to support their broad statement.

1 Q. That's not what I asked you.

2 MR. MILLER: Objection. That is what
3 you asked.

4 A. Would you ask it again, please.

5 MR. MORIARTY: You will not find that
6 statement from me on this record, Pete. Don't do
7 that.

8 MR. MILLER: I will do that.

9 MR. MORIARTY: And don't coach him.

10 MR. MILLER: And don't point at me and
11 tell me not -- what not to do.

12 MR. MORIARTY: Don't coach him.

13 MR. MILLER: I'm not coaching anything.
14 I'm pointing out what your -- the flaw of your
15 statement was.

16 You asked about the top of the
17 observation and the bottom.

18 MR. MORIARTY: Pete -- Pete, this is
19 federal court. Objection and your basis. Don't
20 start this. Okay?

21 MR. MILLER: No, Matt. I'm -- you
22 started this. I'm just trying to point out your
23 flaws, Matt.

24 Q. I asked you a very specific question.

25 A witness named Chuck Koon, a quality assurance

1 expert at Mylan, said that the FDA's Turbo
2 software --

3 A. I'm not -- first of all, I'm not
4 familiar with the FDA's --

5 Q. Okay.

6 A. -- Turbo software.

7 Q. I'm just asking you if you agree with
8 Mr. Koon.

9 He said that this statement about drug
10 products failing to meet established specifications
11 is essentially the FDA's kicking out the regulation
12 language.

13 And I asked you if you agreed with
14 that. And you said you didn't know.

15 A. I don't know.

16 Q. Okay. FDA is charged with protecting
17 public health, is it not?

18 A. Yes. It certainly is.

19 Q. Sometimes, when the FDA acts, it has to
20 be flexible and act quickly to carry out its duty to
21 the public.

22 Do you agree with that?

23 A. Yes.

24 Q. In your experience, does FDA sometimes
25 act too hastily in ordering recalls of products?

1 A. In ordering recalls, my experience is
2 they do not act too hastily.

3 Q. In your experience, do they ever
4 overreach?

5 A. Could you explain what you mean by
6 "overreach"?

7 Q. Plain English definition of it.

8 A. Overreach what?

9 Q. Okay. Well, for example, in -- in the
10 situation that you had with your HIV home health
11 testing, was there some other fix for the problem,
12 other than a recall, available?

13 A. Other than a recall? Yeah. We could
14 have -- I suppose we -- no. There was no logical
15 fix.

16 We could have gone out and inspected
17 competitive product. First of all, we have no right
18 to look at competitive product.

19 But conceivably, we could have gone and
20 had our entire sales force go out, look for all the
21 product they could find, which may or may not be all
22 the product, and then pull the mailers off.

23 But the issue is compounded because
24 people have the product. They may have the wrong
25 mailer. They may keep the product for months. So

1 the -- the only responsible behavior is to recall.

2 Q. All right.

3 A. And may I say that, as part of the
4 companies that I've worked for, we would take a
5 very, very conservative approach to recalls,
6 probably far more conservative than the FDA would.

7 Q. All right. When you were at J&J, what
8 percent of your personal work involved solid oral
9 dose?

10 A. It depends upon the point in my career.
11 There was a three-year career --

12 Q. Overall.

13 A. Overall? 8, 11, doing it recently.
14 I'd say 12 years.

15 Q. Okay. And overall, J&J has had recalls
16 of solid oral dose tablets or capsules even while
17 you worked there; correct?

18 A. The \$60 billion Johnson & Johnson
19 company most certainly has had recalls.

20 Q. Okay. So I think there was Tylenol
21 recall back in the '80s?

22 A. '83. I was somewhat involved in that.

23 Q. Okay. And did -- did J&J ever
24 internally assess, to your knowledge, what
25 percentage of the Tylenol that was recalled was

1 actually somehow outside its specifications?

2 A. But that wasn't the issue.

3 The issue was whether or not it was
4 tampered by a -- an individual.

5 Q. Okay. What percentage of it was
6 tampered with?

7 A. I don't know. I don't recall.

8 Q. Far less than --

9 A. Less than 100.

10 Q. 100 instances?

11 A. No. Far less than probably -- no. Far
12 less -- no. The number of instances where -- if I
13 was going to guess, I would guess less -- less than
14 10.

15 In other words, they only had a few
16 instances where the product was tampered with by
17 whoever the felon was.

18 Q. Sure. Did -- in your career there at
19 J&J, did they have recalls of other solid dose
20 products, solid oral dose products?

21 A. I'm sure they did. I can't recite who
22 they were. They weren't involved with companies
23 that I had responsibility for.

24 Q. All right. But in those instances,
25 either J&J could have voluntarily done a recall or

1 FDA could have requested a recall, even if just a
2 small percentage of the solid oral dose that had
3 made it to market was possibly outside its
4 specifications; right?

5 A. That is correct. That is possible.

6 Q. So when we talk about, I use the term
7 "hasty" or "overreaching," you would agree that
8 sometimes recalls are conducted even though the
9 possibility of an actual defect and harm to the
10 public is small; correct?

11 A. I would answer that question not in
12 that way.

13 I would answer the question as we don't
14 know, and we would take a conservative approach and
15 pull it back. And as part of the investigation
16 subsequently, we'd get some knowledge of the breadth
17 of the issue.

18 Q. All right. It's sort of an abundance
19 of caution thing.

20 Is that how you are referring to being
21 conservative?

22 A. That's -- that's one way.

23 Q. All right. Your Reference B, Number 2,
24 is 21 Code of Federal Regulations Part 210 and 211
25 regarding GMPs; correct?

1 A. That is correct.

2 Q. And I'd like -- do you have a printout
3 version of it?

4 A. No, I don't. Actually -- no, I don't.

5 Q. All right. This is your Tab -- your
6 Reference 2.

7 MR. MORIARTY: Pete, you can come over
8 here if you need to see it.

9 Q. Do you see that this is Part 210 of the
10 GMPs?

11 A. Correct.

12 Q. And the next page, in 210.1,
13 Section B --

14 A. Yes, sir.

15 Q. -- it says: "The failure to comply
16 with any regulations set forth in this part, and in
17 parts 211 through 226 of this chapter, in the
18 manufacturing, processing, packing or holding of a
19 drug shall render such drug to be adulterated under
20 Section 50182B"; correct?

21 A. Yes.

22 Q. And then the last part of this long
23 sentence says: "Shall be subjected to regulatory
24 action"; correct?

25 A. That's exactly what it says.

1 Q. All right. And what this section of
2 the CFR is about is the regulatory powers of the
3 FDA.

4 Is that right?

5 A. That's correct.

6 MR. MILLER: Object to the form. The
7 document speaks for itself.

8 Q. To your knowledge.

9 A. Yes.

10 Q. Okay. You -- I didn't see anything
11 about medical school, internships or residencies on
12 your resume.

13 You're not a physician; right?

14 A. That is correct.

15 Q. So I assume that you are not going to
16 be testifying about whether specific plaintiffs'
17 injuries had anything to do with defective Digitek;
18 correct?

19 A. That is correct.

20 Q. As far as I can understand your report
21 and, obviously, the summary at page 23, your role is
22 to talk about whether Actavis complied with certain
23 good manufacturing practices.

24 Is that right?

25 A. That is correct.

1 Q. And for this definition of
2 adulteration, you are relying on CFR 351(b), I
3 assume?

4 A. If that's what it says, yes.

5 Q. And this is Tab 5 of your Reference B.
6 Is that right?

7 A. I assume it's correct.

8 (Exhibit 39, FDA Printout, was marked
9 for identification.)

10 Q. Now, that's Exhibit 39. This is a
11 printout from the FDA's website.

12 Have you ever seen this before?

13 A. Let me just take a look at it.

14 I believe I have.

15 Q. And this particular section is called
16 "Facts About Current Good Manufacturing Practices";
17 correct?

18 A. That's correct. This is -- this is
19 somebody's interpretation of what the facts are.
20 It's not a guidance document. It is a page in a --
21 in a website.

22 Q. But it is a page from the FDA's
23 website?

24 A. Absolutely.

25 Q. All right. Now, go down to the second

1 title that says "Why Are cGMPs So Important?"

2 MR. MORIARTY: When you type cGMP, the
3 C is small and the GMP is large.

4 Q. The second sentence says: "In most
5 instances, testing is done on a small sample of a
6 batch (for example, a drug manufacturer may test 100
7 tablets from a batch that contains 2 million
8 tablets) so that most of the batch can be used for
9 patients rather than destroyed by testing."

10 Do you agree with that?

11 MR. MILLER: Again, I would object. I
12 would ask you to give him an opportunity to read the
13 whole paragraph before you ask him about a
14 particular sentence inside a paragraph so he can put
15 it in context.

16 Q. Okay. Do you need to read more or are
17 you ready to answer questions?

18 A. I would like to read it.

19 Q. You can read the whole thing. Let me
20 know when you're ready.

21 A. I've read it.

22 Q. Let's go down to -- and let me linger
23 there a second.

24 From your experience, that is true in
25 practice; correct?

1 I mean, a manufacturer can't test them
2 all, or there'd be nothing left to sell; correct?

3 A. That's correct. Of course.

4 Q. So I assume at J&J, the products that
5 you were involved with had sampling plans?

6 A. Most certainly.

7 Q. All right. And at some point in the
8 validation process or through inspections, FDA was
9 aware of what those sampling plans were?

10 A. Well, if they reviewed them, yes.

11 Q. Okay. Let's go down to the fourth
12 heading, "If a Manufacturer is Not Following cGMPs,
13 Are Drug Products Safe for Use?"

14 Go ahead and read that whole section,
15 because I'm going to ask you about it.

16 A. Okay.

17 Okay. I've read it.

18 Q. The first two sentences of that section
19 essentially state what's in these regulations in
20 Tabs 2 and 5 from your Reference B; right?

21 A. Okay.

22 Q. That if a drug is not manufactured in
23 compliance with cGMP, the FDA considers it
24 adulterated; correct?

25 A. That's correct.

1 Q. The next sentence says: "It does not
2 mean that there is necessarily something wrong with
3 the drug."

4 Do you agree with that?

5 A. I think it's poor wording.

6 Q. How do you think it's poor wording?

7 A. Because the quality of a drug is
8 dependent upon executing a series of steps, starting
9 in the development process, going through -- going
10 through development process, going through to
11 technical transfer, going through to process
12 validation, going through to routine -- writing
13 procedures, etcetera, that are in place to control
14 the quality, and then ultimately, just making sure
15 that it's okay by taking a sample.

16 Because, of course, you don't know --
17 you don't know what you don't know, but what you do
18 know is that at least you've looked at X number of
19 samples, and those samples were good.

20 Since you've based your sampling upon
21 your validated state, and you know you have content
22 uniformity, you know that all the tablets are coming
23 off the -- the production line within specification,
24 therefore justifies, as the last step, taking a
25 sample.

1 So the -- I think this is poor wording.

2 Q. Okay. Well, let's -- let's get to the
3 bottom of what it's saying.

4 The FDA could call a particular batch
5 of tablets adulterated, could it not?

6 A. Yes.

7 Q. If it found a cGMP violation; correct?

8 A. Yes.

9 Q. All right. Let's stick with one batch
10 for the time being.

11 A. Certainly.

12 Q. But if FDA -- if the manufacturer had
13 done United States Pharmacopeia testing on tablets,
14 and then the FDA itself did USP testing on tablets
15 from that same batch and confirmed that they were
16 within the USP's specifications, there would have
17 been nothing wrong with those tablets; correct?

18 A. There would be nothing wrong with the
19 tablets that they tested.

20 Q. Okay. And when there is --

21 A. If --

22 Q. When --

23 A. If -- may I say an if?

24 If there was a valid test method done
25 by a qualified individual.

1 So if we assume that the FDA and all
2 these other tests that were done were qualified,
3 that they had a validated test method, then we can
4 assume, and it's fair to assume that the units that
5 they tested, those tablets, those bottles, whatever
6 they tested to get individual samples are within the
7 specification.

8 Q. Okay.

9 A. If it's determined that it is.

10 Q. And the FDA allows you to draw certain
11 conclusions from that because it's an appropriate
12 sampling size; correct?

13 A. Tell me what you -- are you saying is
14 the conclusion.

15 Q. All right. Well, let me -- let me ask
16 you: If FDA -- do you know what a 484 is?

17 A. No. I am not familiar with that.

18 Q. You don't know what a 484 is?

19 A. I said --

20 MR. MILLER: Objection. Asked and
21 answered.

22 Q. FDA comes to Johnson & Johnson and
23 decides to take a sample from you of your product
24 for independent testing.

25 A. Right.

1 Q. Do you know what that process is?

2 A. Do -- I heard of it. I haven't been
3 involved in it.

4 Q. All right.

5 A. Regulatory affairs department would
6 interact with the FDA, not the quality assurance
7 department.

8 Q. Well --

9 A. In -- in a situation like that.

10 Q. Well, if FDA independently tested a J&J
11 product that you were involved in, what conclusions
12 would -- and it passed all the specifications, what
13 conclusions would you, at Johnson & Johnson, draw
14 from that?

15 A. I would draw a conclusion that they
16 took X number of samples, and the samples that they
17 took were within specifications.

18 Since I know that my process is well
19 developed, well characterized, since I know I have a
20 validated process, since I know I have validated
21 test methods, since I know I have qualified
22 individuals conducting all of these studies, then I
23 can make a conclusion that their test results
24 confirmed that which I knew to begin with.

25 Q. So it's good news; right?

1 MR. MILLER: Object to form.

2 Q. Okay. I'll use something more
3 scientific.

4 It corroborates your processes and
5 testing, doesn't it?

6 A. Yes. It certainly does.

7 Q. I didn't see on your Reference B that
8 you looked at any of the process validation for
9 Digitek.

10 Did you look at the process --

11 A. Yes.

12 Q. -- validation documents for Digitek?

13 A. I looked at two process validations.
14 They were rather old. 1993, I believe, for
15 .5 milligram Digitek. And there was -- there may
16 have been another one. I don't recall.

17 Q. Well, and that was submitted to the FDA
18 for purposes of the ANDA; correct?

19 A. Perhaps. I would assume that it was.
20 I don't know. It doesn't say this was submitted. I
21 don't have the submission.

22 Q. Did you ever see anywhere in the
23 material that you reviewed a specific reference by
24 FDA that Digitek testing methods, like MOI 145, were
25 not validated?

1 A. I believe there was one or two test
2 methods not properly validated.

3 Q. Okay. Find it. I want to -- I want to
4 hear from you where in all the material you reviewed
5 there is a single reference by the FDA to a --

6 A. Test method.

7 Q. -- to a test method for finished
8 tablets not being validated.

9 A. Well, you just added "finished
10 tablets."

11 I would -- I would assume that, based
12 upon your questioning and your challenge, that I
13 would not find that.

14 So -- so I may have misspoken in terms
15 of recalling a test method validation
16 non-conformance.

17 Q. Let's go to the second paragraph in
18 Exhibit 39 in the section "If a Manufacturer Is Not
19 Following cGMPs, Are Drug Products Safe for Use?"

20 A. Okay.

21 Q. About two-thirds of the way down, it
22 says: "The impact of cGMP violations depends on the
23 nature of those violations and on the specific drugs
24 involved."

25 Do you agree with that?

1 A. I think it's poor wording.

2 I would have to say I agree with it.

3 Q. All right. The next sentence says: "A
4 drug manufactured in violation of cGMP may still
5 meet its label specifications."

6 Do you agree with that?

7 A. Of course.

8 Q. And the remainder of the sentence says:
9 "And the risk that the drug is unsafe or ineffective
10 could be minimal."

11 A. Of course.

12 Q. Do you agree with that?

13 A. Of course.

14 Q. So let me see if I state it another
15 way, if I understand what these regs mean.

16 The finding of adulteration because of
17 a cGMP violation at most reflects a possibility that
18 out-of-specification drugs were produced; correct?

19 MR. MILLER: Object to form. Misstates
20 previous testimony.

21 A. You can repeat the question. But I
22 don't think it's correct. Would you repeat the
23 question?

24 MR. MORIARTY: Can you read it back,
25 please?

1 (Requested portion is read.)

2 A. No. No, that is not correct.

3 Q. Okay. Adulteration is a regulatory
4 definition; correct?

5 A. The FDA defines adulteration in the
6 CFR.

7 Q. All right. And whether a particular
8 drug is within or without its specifications is
9 actually something you can test to determine;
10 correct?

11 A. No.

12 Q. You can't?

13 A. No. What you can determine is that
14 taking a sample, you have a certain level of
15 probability if the product tests acceptably.

16 You have a certain level of probability
17 and a confidence interval that the product is
18 acceptable.

19 You don't know what you don't know.
20 You haven't tested them all.

21 If you tested them all, and they were
22 validated test methods, and they were a qualified
23 individual that did the test, I think a fair
24 assumption would be that all of them would be within
25 specification.

1 Q. All right. Well, let's just assume
2 that in the 484 process, the FDA comes in and takes
3 a sample of a solid oral dose product off a pharmacy
4 shelf.

5 A. Sure.

6 Q. And tests a certain number of tablets
7 for dissolution, assay, content uniformity within
8 the United States Pharmacopeia guidelines.

9 A. Um-hum.

10 Q. Okay? And they are all within --

11 A. And in accordance to your submission.

12 Q. Yes. And they're -- and they're all
13 within the USP parameters for that product.

14 A. Assuming it's a USP.

15 Q. Yeah. What is -- I mean, what is the
16 confidence interval that the FDA would have
17 regarding that particular tested batch?

18 A. Very low.

19 Q. Very low?

20 A. Yes.

21 Q. So why do they do it?

22 A. You have to ask them.

23 Q. And you've --

24 A. Because it will -- it would conceivably
25 detect gross issues.

1 When I say "gross issues," gross of the
2 highest order.

3 Q. Have you ever been involved personally
4 at J&J with the 484 process with the FDA?

5 A. Of the sampling process, no. If there
6 was a non-conformance, I would have heard about it
7 instantly.

8 Q. Have you ever seen in any of the
9 material that you reviewed a final agency
10 determination that Digitek, that single product, was
11 adulterated?

12 A. I don't recall.

13 Q. Would you like to look?

14 A. No. It's too voluminous. We're trying
15 to keep this within a day or two.

16 Q. Well --

17 A. I don't have the time -- I mean --

18 Q. It may be -- it may be time-consuming,
19 but it's awful important for me to know.

20 A. I -- I will tell you that in reviewing
21 the documents, I cannot recall an instance where
22 they said -- specifically used the word Digitek is
23 adulterated, separating that out.

24 Q. Okay. We typically take breaks every
25 hour to hour and a half.

1 You let me know when you're ready for
2 the first break.

3 A. I'm fine.

4 Q. Okay. Do you know what the FDA's
5 application integrity policy is?

6 A. No.

7 Q. Are you familiar with the CFRs
8 pertaining to accuracy of documents like batch
9 records, annual reports and things of that nature?

10 A. No, I'm not familiar with it.

11 Q. Well, what -- do you know anything
12 about the F -- what the FDA would do to a company if
13 it reasonably suspected that the company was
14 falsifying data either in an NDA or ANDA or a
15 run-of-the-mill record for production?

16 A. And you're asking me do I know anything
17 about that?

18 Q. Yes.

19 A. Do I know anything? I know logic, that
20 the -- it would be a serious offense, and I would
21 assume criminal -- potential criminal prosecution.

22 Q. I didn't see anything in your report
23 referring to any FDA 483s or warning letters about
24 the integrity of Actavis's applications or data.

25 Did I miss a reference?

1 A. No. You did not miss a reference.

2 Q. Did you -- do any of the references in
3 your Appendix B contain FDA warnings or citations
4 about data integrity regarding Digitek?

5 A. Could you repeat the question?

6 Q. Yes. In your Appendix B, this thing
7 we've been talking about where you have all these --

8 A. Right. The references.

9 Q. -- things you referred to, do the 483s
10 or warning letters or EIRs in your Appendix B
11 contain FDA observations or findings about data
12 integrity concerning Digitek?

13 A. I don't recall any.

14 MR. MORIARTY: Let's -- there's just a
15 couple minutes left on this tape, so let's take our
16 break now.

17 THE VIDEOGRAPHER: Please stand by. We
18 are going off the record. It is 9:58 A.M. This
19 ends Tape Number 1.

20 (Recess was taken.)

21 THE VIDEOGRAPHER: We are back on the
22 record. The time is 10:12 A.M. This is the
23 beginning of Tape Number 2.

24 Q. All right, Mr. Kenny.

25 Have you ever heard of Quantic

1 Regulatory Services?

2 A. I've heard the name.

3 Q. Do you know anything about their
4 reputation in the industry?

5 A. No. I really don't.

6 Q. Do you know anything about their
7 reputation with FDA?

8 A. No. I have no idea. I know they're a
9 consulting firm. And I believe they're rather
10 large. That's it.

11 Q. Are you familiar with any Actavis batch
12 record reviews done by Quantic Regulatory Services?

13 A. Specifically, no.

14 Q. And I didn't -- this is Exhibit 23.

15 (Exhibit 23, Letter dated 12/24/07 from
16 Scott Talbot, was marked for identification.)

17 Q. First of all, are you aware that in the
18 early 2007 FDA warning letter, they requested that
19 Actavis get independent batch record review?

20 A. Yes. I'm aware of that.

21 Q. Have you ever seen Exhibit 23 before?

22 MR. KAPLAN: Do you have an extra?

23 MR. MORIARTY: I thought I passed one
24 down.

25 A. When I look at the cover, I say no.

1 I'm pretty sure I haven't seen this.

2 Q. All right.

3 A. It's a lot of blank.

4 Q. It's a lot of redactions. I understand
5 that.

6 So -- first of all, you see that the
7 cover of Exhibit 23 is a letter dated December 24,
8 2007 to a compliance officer at FDA from Scott
9 Talbot, who was then site head of quality at Actavis
10 Totowa; correct?

11 A. Correct.

12 Q. And then attached, I will represent to
13 you that these are Quantic records regarding batch
14 record review.

15 And, if you look at Bates page
16 1867202 -- I think you're -- you're on the same
17 page -- on that page, Items 35 through 39 are
18 specific Digitek batch records; correct?

19 A. It appears, yes.

20 Q. And then later, at Bates page starting
21 1867214 --

22 A. Okay. Sure.

23 Q. -- and spilling over into the next
24 page, between Items 47 to 80, inclusive, are all
25 specific Digitek batch records; correct?

1 A. Yeah. Items 47, whatever you want to
2 call it, through 80 are Digitek.

3 Q. All right. And have you seen the
4 Quantic Regulatory Services protocol that they used
5 for the review of the Digitek batches?

6 A. No, I did not.

7 Q. And I will represent to you that if you
8 count them all up, they looked at 39 Digitek batch
9 records.

10 Would you trust me on that?

11 A. I trust you implicitly.

12 Q. And do you know how many of those 39
13 were of what ultimately became recalled batches?

14 A. In 2007, no. I -- I couldn't determine
15 that.

16 I'd have to look at the number of
17 batches that were within expiration, is the only way
18 I could tell.

19 Q. All right. I want you to assume that
20 19 of those 39 were of batches that were ultimately
21 recalled.

22 Okay?

23 A. Okay.

24 Q. And go back to the cover page of 23.

25 A. Sure.

1 Q. Actavis tells the FDA that Quantic's
2 ultimate conclusion was: "On December 21, 2007,
3 Quantic provided Actavis with a statement indicating
4 the audit was complete, and the manufacturing and
5 laboratory records have reliably confirmed the
6 identity, strength, quality and purity of the
7 marketed products."

8 Do you see that?

9 A. I certainly do.

10 Q. Do you have any basis on which to
11 disagree with Quantic's assessment in that regard?

12 A. Well, I have to qualify this.

13 Q. Well, can you answer my question first?
14 And then --

15 A. Do I have any --

16 MR. MILLER: Objection.

17 MR. MORIARTY: He can qualify it. I
18 want a yes or no, and then he can qualify it.

19 A. Well, repeat it one more time, please.

20 Q. Do you have any basis to disagree with
21 Quantic's conclusion regarding the 39 batches that
22 they --

23 A. Yes, I would.

24 Q. Okay. What's the basis?

25 A. Can I reread this out loud? It says:

1 "Quantic provided Actavis with a statement
2 indicating the audit was complete, and manufacturing
3 and laboratory records have reliably confirmed the
4 identity, strength, quality and purity of the
5 marketed products."

6 I would disagree with the word
7 "reliably."

8 Q. Why?

9 A. Because they took a -- they looked at a
10 batch record that indicated that there was no major
11 issues, assuming there were no major issues, and if
12 there were major issues, the batch would have been
13 held and reviewed.

14 The assumption there is that the batch
15 records contained accurate information. The
16 assumption is that the test methods that were used
17 were validated. The assumption is that the process
18 is validated.

19 And if you form all the -- the
20 assumption is that the equipment is calibrated. The
21 assumption is that people are properly trained.

22 Now, if all of those things were in
23 place, and then I looked at -- if I was Quantic,
24 looked at the batch records, I would say, you know,
25 they have a reliable process. They have reliable

1 testing. Etcetera, etcetera. Based on all that
2 reliable good stuff, I will say that, hey, I can say
3 reliably, you know, this sample -- I'm sorry, this
4 sample -- these batch records make me feel good
5 about it.

6 Q. Okay. But if I'm correct, you've not
7 only never seen Exhibit 23, and you've never seen
8 Quantic's protocol, and you've only seen three batch
9 records, compared to at least their 39; correct?

10 A. Yes.

11 Q. And I didn't see anywhere in your
12 report that indicated that any process for Digitek
13 was not validated. Have you made an observation --

14 MR. MILLER: Objection.

15 MR. MORIARTY: Let me finish my
16 question.

17 MR. MILLER: Sure.

18 MR. MORIARTY: Then he gets to object.
19 Then you get to answer it.

20 Q. I didn't see any observation in your
21 report indicating that any process for Digitek was
22 not validated.

23 Have you given that opinion in your
24 report?

25 MR. MILLER: Object to form.

1 You can answer.

2 A. Okay. The process that can produce
3 defective product is not a validated process.

4 MR. KAPLAN: I'm going to object and
5 move to strike that answer as not being responsive
6 to the question you were asked.

7 THE WITNESS: Okay.

8 MR. MILLER: And continue on with the
9 same answer.

10 He can object, but you can still
11 continue on.

12 A. Okay. I don't -- I --

13 Q. What I'm asking is: I didn't see
14 anywhere in your report to indicate that any Digitek
15 process was not validated.

16 A. Okay. To answer your question
17 specifically, I did not use the term Digitek in
18 terms of a non-validated process --

19 Q. Okay.

20 A. -- specifically in here.

21 Q. Okay. Do you have any evidence that
22 the FDA did not accept Actavis's and Quantic's
23 findings as exhibited by Exhibit 23?

24 A. No. I have no evidence.

25 Q. That's Exhibit 24.

1 A lot of paper.

2 A. Um-hum.

3 Q. And I'm not going to take you through
4 all of it.

5 Now, in your Exhibit -- I'm sorry --
6 your Appendix B, I didn't see a reference to any FDA
7 Form 484s.

8 A. That's correct.

9 Q. Did you review any FDA Form 484s?

10 A. No, I did not.

11 Q. Well, let's look at Exhibit 24.

12 (Exhibit 24, FDA Collection Report for
13 Sample Number 377410, was marked for
14 identification.)

15 Q. Is that for Sample 377410?

16 A. Yes.

17 Q. And if you look at the narrative, does
18 it indicate that in February of 2007, FDA took two
19 bottles of 100-count, 125 microgram Digitek from
20 Actavis?

21 A. Could you point to where that is?

22 Is it here?

23 MR. KAPLAN: It's on the first page,
24 under "Description of Sample."

25 Q. If you go to page 3 of 3 of Exhibit 24,

1 it says: "Method of Collection."

2 Do you see that?

3 A. Yes, I do.

4 Q. Okay. So here, they took 200-count
5 bottles of 125 microgram Digitek from the firm's
6 inventory. And then it gives the Actavis batch
7 number; correct?

8 A. It appears to, yes.

9 Q. 70078 A1.

10 Do you see that?

11 A. Yes.

12 Q. And then FDA had an opportunity,
13 presumably, to test as much of this as they wished;
14 correct?

15 A. I presume yes. Sure.

16 Q. All right. And do you know whether or
17 not they used United States Pharmacopeia testing
18 standards for Digoxin?

19 A. I don't specifically know what they
20 did.

21 Q. Have you ever looked at the USP
22 reference standards for the monograph for Digoxin?

23 A. Not for Digoxin.

24 Q. Have you ever looked at the general USP
25 standards for content uniformity?

1 A. Yes.

2 Q. And assay?

3 A. Yes, sir.

4 Q. All right. But here, ultimately, based
5 on whatever they tested, they say: "All methods are
6 compendial and follow USP 29-NF24, page 704, Digoxin
7 Tablets Monograph."

8 Do you see that?

9 A. Where?

10 Q. Under "Remarks" on page 3.

11 A. Yes. With the exception of impurity
12 testing.

13 Q. Which they use a house standard; right?

14 A. "First in-house method is the limit
15 test... utilizes relative retention times" -- yes.
16 So they used USP methods, unless stated otherwise.

17 Q. And according to Exhibit 24, did all
18 the samples that they tested from this batch
19 passed -- pass?

20 A. I'm going to hunt for it. Maybe you
21 can point to it.

22 Q. Yeah. I have to hunt myself.

23 A. I think it's a fair assumption to say
24 they passed, or there would have been tremendous
25 issues.

1 Q. Okay.

2 A. I will accept that it says passed
3 somewhere in here.

4 Q. All right. So what -- do you think
5 that's significant at all?

6 A. Could you -- you know, could you define
7 what you mean by -- be more specific in terms of
8 "significant"?

9 Q. Well, first of all, do you know whether
10 or not Batch 70078 A1 was among the recalled
11 batches?

12 A. I -- since it was a 7, it probably was
13 recalled.

14 Q. And as far as your opinions in this
15 case, do you find FDA's testing and passing of a --
16 of a recalled Digitek batch significant at all?

17 A. Well, they don't test and accept. What
18 they do is they test, they get acceptable results,
19 and they don't react to it.

20 They don't accept anything. The FDA
21 doesn't accept batches. They don't take that
22 responsibility of accepting a batch.

23 They can get -- they can derive
24 acceptable results. When they do -- let's say they
25 do their surveillance program, and they take some of

1 our product and they test it.

2 They don't find the batch acceptable.

3 What they find is the sample that they tested met

4 specification, and they have no cause for concern

5 because it met specification. They don't accept or

6 reject anything.

7 Q. I understand that. But --

8 A. You used that term "accept." That's

9 all.

10 Q. Well, they -- do these results

11 corroborate Actavis's testing of the same batch?

12 A. Do they corroborate?

13 Well, if -- if Actavis got acceptable

14 results of their sample, the FDA took a small

15 sample, presumably smaller than Actavis's, and they

16 confirmed each other that the -- based upon only the

17 testing that the product is acceptable. But the

18 testing is only a small portion of determination

19 whether a batch is acceptable.

20 Q. I understand that.

21 Isn't it likely, given the Actavis

22 testing and the FDA corroborative testing, that the

23 tablets in Batch 70078 A1 were within the USP

24 specifications?

25 A. I can answer that.

1 Is it probable? I would say that,
2 based upon the fact that they do not have
3 validated -- that in general, they do not have
4 validated processes, based upon in general that
5 25 percent of the equipment is not proper -- not
6 qualified, based upon the lax practices that are
7 done in laboratories, etcetera, etcetera, I would
8 only state -- and this, I am being 100 percent
9 honest here. I'm not trying to, you know -- to, you
10 know, avoid the question.

11 I would -- I cannot state that that
12 batch is in compliance because my entire history of
13 working in compliance is based upon systems working.
14 It's not based upon samples. A sample is a merely
15 confirmatory way of saying guess what, guys? At
16 least we know the three samples that we tested were
17 good.

18 Since they had significant issues with
19 content uniformity in general, it -- it -- I lack
20 the confidence that, in general, they -- they have
21 well validated processes.

22 But I'm talking in general, not
23 specifically to Digoxin. But Digoxin is part of
24 this population, therefore...

25 Q. So, if I really understand what you

1 just said at a global level --

2 A. Yes.

3 Q. -- you are assuming, because of general
4 cGMP violations, that Digitek had some problems;
5 right?

6 MR. MILLER: Object. Misstates
7 previous testimony.

8 It's okay to answer.

9 A. Okay. I don't understand the word
10 "problems," Digitek had some "problems."

11 Q. In your answer, I asked whether it was
12 likely that the batch met USP specifications. You
13 never said anything about that.

14 You said that, for a variety of
15 reasons, you didn't think the batch was likely in
16 compliance.

17 What do you mean by "in compliance"?

18 MR. MILLER: Object to form.

19 A. That the systems and procedures that
20 are in place that -- that formed the basis for
21 testing -- no -- formed the basis for determining
22 acceptability of the batch, if those are faulty, and
23 they've shown themselves to be having a lot of
24 issues, I cannot make the assumption that taking
25 samples from the FDA, taking samples from whoever --

1 I can't make the assumption that that product is
2 acceptable.

3 Q. All right. What do you mean by
4 "acceptable"?

5 A. "Acceptable," meaning meets
6 specification each and every time, each and every
7 unit.

8 Q. Okay. What I'm trying to find out --
9 and let's go back to Exhibit 39. It says here: "A
10 drug manufactured in violation of cGMP may still
11 meet its label specifications."

12 And you agreed with me on that?

13 A. Yes. I agree with that.

14 Q. Okay. I want to talk about the labeled
15 specifications.

16 A. Surely.

17 Q. Okay. First of all, have you seen any
18 test results of any type to indicate that Batch
19 70078 A1 did not meet its labeled specifications?

20 A. I don't believe I have seen any
21 information.

22 Q. All right. Now, can you please show me
23 anywhere in all the material that you reviewed
24 anyplace where the FDA said that Digitek did not
25 have validated manufacturing or testing processes?

1 A. Well, the 25 percent of the equipment
2 was not qualified. It's in the 43. I think it was
3 2004, perhaps. That's a significant issue.

4 Q. Are you finished with your answer?

5 A. I certainly am.

6 Q. Show me anywhere in the material that
7 you reviewed anyplace that said that any equipment
8 used to make Digitek was not qualified.

9 A. I don't know what the blenders,
10 etcetera that were used as examples of not being the
11 correct IQ OQ, which is installation qualification,
12 operation qualification and performance
13 qualification.

14 I can't link those two between the
15 manufacturing of Digitek and those particular pieces
16 of equipment. I'd have to -- I'd have to do much
17 more research.

18 Q. So sitting here today, you don't know
19 that any Digitek equipment was found to be not
20 qualified by the FDA; correct?

21 A. Yes. Based upon what I've reviewed.

22 Q. All right. Then let me go back to my
23 first question, now that we've taken care of
24 equipment.

25 Show me anywhere in all the material

1 that you've reviewed, please, where FDA specifically
2 says that there is a Digitek manufacturing or
3 testing process that is not qualified or validated.

4 A. All right. The way I would answer that
5 is that the only evidence that I have seen where a
6 process is validated was done, I believe, in '93.

7 I glanced through it. And the reason I
8 only glanced through it is whatever work was done in
9 '93 is of -- of little use to batches produced 13,
10 14 years later. They may have done great work.

11 So I have yet to see any
12 well-constructed validation studies. I will assume
13 that between '93 and the production of these batches
14 that they didn't do them because I haven't seen it.

15 Q. Well, there's a lot of things you
16 haven't seen. But we'll get to that later.

17 Is there an FDA reg that says
18 specifically that these processes have to be
19 revalidated?

20 A. Is there a specific reg? I'd have to
21 look at -- at 21 CFR.

22 Can I glance at it? I do have a copy.

23 Q. You have it among your materials?

24 A. No, I don't.

25 Q. I've never seen one, but perhaps you

1 know of one.

2 A. It's in there someplace.

3 MR. MILLER: We had it out once -- once
4 already.

5 Q. Well, FDA inspected Actavis on a number
6 of occasions for a variety of reasons between 1998
7 and 2008, did they not?

8 A. 1998 and -- yes.

9 MR. MILLER: Matt, you asked him a
10 question. And he wanted to answer if he could see
11 the CFR.

12 MR. MORIARTY: I'm changing the
13 question. I don't want to dig for the reg. Okay?

14 Q. They did inspect a number of times for
15 a number of reasons over those 10 years?

16 A. Yes.

17 Q. And they had an opportunity to see and
18 observe whether Digitek processes and equipment were
19 validated or not validated; correct?

20 A. Correct.

21 Q. And even in 2008, when the focus was on
22 a Digitek batch, 70924, FDA never said in the 483 in
23 May of 2008 that Digitek processes and equipment
24 were not validated, did they?

25 A. I believe that's accurate.

1 Q. And you said something --

2 A. But they may not have looked for it.
3 They didn't look for everything. They went in.
4 What the FDA does, they look for examples. They
5 don't look to do a comprehensive review.

6 Once they find examples, they make the
7 assumption, and it's certainly a reasonable
8 assumption, that that particular quality system is
9 in violation of GMP.

10 They have found enough evidence so that
11 you need to go back, as the manufacturer, the
12 tester, to go back and do a comprehensive review of
13 that quality system, since you've shown that it's
14 unreliable, what you're doing.

15 You need to go back and do a
16 comprehensive and then determine whether or not
17 you're in compliance.

18 So, if it were me, and I found out,
19 which would not happen, that I had 25 percent of my
20 equipment that was not qualified, then I would go
21 back personally and take a look at all those things,
22 including process validation, which is the
23 culmination of all of these development events.

24 MR. KAPLAN: With all due respect to
25 the witness, I'm going to move to strike your last

1 answer because you're not responsive to the question
2 that Mr. Moriarty asked you.

3 THE WITNESS: It's not on purpose.

4 MR. KAPLAN: Then on purpose, if you
5 would, listen carefully to his questions, and try to
6 answer just the question that he asks.

7 THE WITNESS: I think I --

8 MR. MILLER: You've answered it
9 perfectly, Mark. He's allowed to object. But you
10 answered it perfectly, and keep going.

11 MR. KAPLAN: And I move to strike
12 counsel's comments as inappropriate.

13 MR. MORIARTY: Can I go on?

14 THE WITNESS: In all fairness, I
15 thought I did.

16 Q. What independent analysis did you do to
17 determine whether Digitek manufacturing and testing
18 processes were validated?

19 A. In -- in looking at, for example, the
20 batch with the double-thick tablets, that
21 particular -- the evidence that I was shown for that
22 particular batch was horrendous.

23 It showed more errors than any batch
24 record I -- I won't say I've ever seen. It ranks up
25 there.

1 The level of investigation as a
2 determination of a, quote, validated --

3 Q. Excuse me.

4 MR. MILLER: No.

5 Q. I need to stop you. What I'm asking is
6 not your overall opinion of their sloppiness or
7 their GMP.

8 I want to know what independent
9 analysis you did whether they were validated. Not
10 whether they made mistakes or -- whether they were
11 validated.

12 A. I'm trying to answer.

13 MR. MILLER: And I'm going to object.
14 Excuse me, Mark. I think the answer did go to the
15 question.

16 MR. MORIARTY: That's fine. Let him
17 answer.

18 MR. MILLER: I'm going to let him
19 answer, Matt.

20 Q. Go ahead.

21 A. Did I find -- one more time.

22 Q. I want to know what -- okay. You've
23 already told me that nowhere in FDA's 483s or
24 warning letters did they make a specific comment
25 that FDA -- or Digitek processes were not validated

1 or that Digitek equipment was not qualified.

2 What independent assessment did you do
3 about validation? Not about GMP, about validation.

4 A. You mean a validation study?

5 Q. Yes.

6 A. The only thing that I read concerning
7 Digitek was a 1993 process validation study.

8 Q. Okay.

9 A. That's it.

10 Q. All right. Now, among your answers
11 earlier, you said that there were lax practices in
12 the lab.

13 Can you show me anywhere in the
14 material that you reviewed where FDA said that there
15 were any lax laboratory practices regarding Digitek?

16 A. I'd have to look at the -- Digitek?
17 I'd have to look at the -- all of the 483s, the
18 EIRs. I'm sorry. I -- I don't recall.

19 MR. KAPLAN: That's what you did,
20 didn't you?

21 A. I did, but I don't recall. I was -- my
22 focus was not specifically only on Digitek.

23 My -- my focus is first to understand
24 what kind of systems and procedures are in place.
25 Is this a well-controlled company?

1 Now, if --

2 MR. KAPLAN: I'm going to move to
3 strike that as not responsive.

4 All he asked you was where did -- did
5 you see any reference to lax laboratory practices re
6 Digitek in anything that you reviewed? That was the
7 question.

8 MR. MILLER: And he's entitled to give
9 an answer.

10 MR. KAPLAN: Yes or no? Did you see
11 any reference?

12 MR. MILLER: Let's answer his question
13 before we get to your question.

14 A. I mean, I'm not trying to avoid the
15 question. Understand, I'm not trying to avoid it.
16 I don't recall any.

17 Q. Mr. Kenny, what I'm trying to do today
18 is be very specific, okay, about Digitek and
19 findings about Digitek by FDA or by you. Okay?

20 (Exhibit 25, FDA Summary Report for
21 Sample Number 448881, was marked for
22 identification.)

23 MR. MILLER: Thank you, Matt.

24 Q. Have you ever seen Exhibit 25 before?

25 A. No.

1 MS. CARTER: Matt, real quick, I have a
2 question about Exhibit 24 and 25.

3 Were these produced in -- in discovery?

4 MR. MORIARTY: We got these from the
5 FDA pursuant to an FOIA request, just like you got
6 most of your documents from the FDA pursuant to an
7 FOIA request. These are not my company's documents.

8 MS. CARTER: Okay.

9 Q. Have you ever seen Exhibit 25 before?

10 A. No, I have not.

11 Q. All right. Is this Sample 448881?

12 A. Oh, I'm sorry. Yes.

13 Q. FDA 484 sampling?

14 A. Yes.

15 Q. Okay. And let's go -- if you go
16 through here, you see that what FDA did was go to a
17 Walmart pharmacy in Indiana and collect two
18 100-count bottles of Digitek 125 micrograms.

19 A. Okay.

20 Q. Is that right?

21 A. I don't see the Walmart part, but
22 the -- I'll assume that what -- so they have
23 samples. They collected them. Okay.

24 Q. Okay?

25 A. Yeah.

1 Q. If you go to the second page, it says
2 "Walmart pharmacy warehouse" down there.

3 Do you see that?

4 A. Please point that to me. "Low-cost
5 generic" -- oh, yeah. Okay.

6 Q. And this was in December of 2007;
7 correct?

8 A. Collection identification. Sample --
9 it says something EB 12307?

10 Q. Yes. December 12, 2007. The same
11 month in which Batch 70294 was on hold; correct?

12 Do you know that?

13 A. I believe that's correct. Wait a
14 minute.

15 Repeat the last part.

16 Q. This is the same month, by coincidence,
17 that Batch 70924, the double-thick batch, was on
18 hold for investigation; correct?

19 A. That is correct.

20 Q. All right. And what FDA did was,
21 again, test pursuant to the United States
22 Pharmacopeia methods. And all these samples passed
23 all the tests to which FDA subjected them.

24 Is that correct?

25 A. I'm going to assume, because in here it

1 says the lab -- the product specifications for
2 identity, dissolution and content uniformity,
3 product meets it.

4 Q. Okay.

5 A. That's on page 1.

6 So I am going assume, you know, not
7 going through this thing, that they would have
8 highlighted whether or not there were any
9 non-compliances, non-conformances.

10 Q. And this was Batch 70298 A1.

11 Is that right?

12 It's in the middle of the second page,
13 under "Manufacturer's Code."

14 A. Yes. 70298 A1, expiration April of
15 2009.

16 Q. Do you know whether this was a recalled
17 batch?

18 A. I will make the assumption that it's
19 recalled because of the batch number.

20 Q. Have you seen any test results of any
21 type to indicate that tablets from Batch 70298 A1
22 did not pass USP testing?

23 A. As finished product test, no, I have
24 not. As a finished product test.

25 (Exhibit 26, FDA Summary Report 448892,

1 was marked for identification.)

2 Q. Handing you what's been marked as
3 Exhibit 26.

4 MR. MORIARTY: Harvey.

5 MR. KAPLAN: Yes, sir. Thank you.

6 Q. We'll get good at reading these by the
7 end.

8 A. I think we are getting better.
9 Can I circle things or not?

10 Q. Sure.

11 MR. MILLER: Is that on the -- you
12 don't want to write on the -- on the copy that's
13 being marked as an exhibit.

14 THE WITNESS: Oh, okay.

15 Q. There's the exhibit copy. You mark
16 whatever you want on it.

17 December 3, 2007, FDA collected Sample
18 448892, again from a Walmart warehouse in Indiana.

19 A. Okay.

20 Q. The same day as the other -- as
21 Exhibit 25.

22 A. All right.

23 Q. And this was 200-count bottles of
24 .250 microgram Digitek; correct?

25 A. Yes.

1 Q. From Batch 70664 A?

2 A. 70664 A1, correct.

3 Q. And this -- all these samples tested
4 appropriately within the specifications?

5 A. Yes. It says: "The product meets
6 specification for identity dissolution and content
7 uniformity."

8 Q. Do you have any evidence, have you seen
9 any evidence to indicate that tablets from that
10 particular batch did not pass USP testing?

11 A. I have no evidence to suggest that it
12 did not pass finished product testing.

13 Q. Had you seen this before, by the way?

14 A. No, I did not. I haven't seen any of
15 the -- I can make a blanket statement. I have not
16 seen those forms.

17 (Exhibit 27, FDA Collection Report for
18 Sample 453913, was marked for identification.)

19 Q. Showing you what's been marked as
20 Exhibit 27.

21 A. Okay.

22 Q. Does it indicate that in February of
23 2008, FDA took Sample 453913?

24 A. 45 -- right. Yes.

25 Q. Was it one 1,000-count bottle of 125

1 microgram Digitek?

2 A. One. Correct.

3 Q. And it was from Actavis Batch 70737 A?

4 A. That's correct. Al.

5 Q. And did all the tests to which FDA
6 subjected these tablets pass the USP criteria?

7 A. I'm trying to find the -- this is a
8 little different.

9 I assume that somewhere, it has that
10 statement.

11 Digoxin, reason for collection,
12 description sample method, how prepared,
13 identification, delivered, remarks. I don't see
14 where it says that.

15 Wait a minute. Let's look in here.
16 Continuation.

17 Okay. If you look on, I don't know,
18 around the third page, page 1 of 1 -- looks like
19 this.

20 Q. Yep.

21 A. Okay. It states that the -- where is
22 it now?

23 Q. "The sample meets USP specifications
24 for identification, content uniformity and
25 dissolution"; correct?

1 A. Correct.

2 Q. Have you seen any evidence to indicate
3 that any samples from Batch 70811 -- I'm sorry --
4 from Batch 70737 A1 did not pass USP testing?

5 A. I see no evidence that the final
6 samples that have been tested, they've all met
7 finished product specifications.

8 (Exhibit 28, FDA Summary Report for
9 Sample Numbers 454866, was marked for
10 identification.)

11 Q. Handing you what's been marked as
12 Exhibit 28.

13 This is February 15, same day as
14 Exhibit 27, Sample 454866; correct?

15 A. 45 -- correct.

16 Q. And this was taken from a McKesson
17 warehouse in Georgia?

18 A. Low-cost generic drug sample survey.
19 I'm looking.

20 I suspect it's here.

21 Q. It's way at the back. Way at the back.

22 A. Oh, okay.

23 Q. The second page from the back. They
24 just send us these out of order.

25 A. I understand.

1 Q. See that? McKesson Drug Company?

2 A. Yes, I do.

3 Q. All right. And this sample also was
4 subjected to USP testing for identification, content
5 uniformity and assay, and it passed; correct?

6 A. Where does it say it passed?

7 Q. Go to the very first page, under "Lab
8 Conclusion" --

9 A. Yes. Right. "The sample meets USP
10 specifications for identity, dissolution and content
11 uniformity." Yes.

12 Q. Ever seen any test results to indicate
13 that Batch 70811 A had out-of-spec tablets?

14 A. I don't recall it. I would assume that
15 no, I have not seen it.

16 Q. Do you know any of the other experts
17 hired by the plaintiffs in this case?

18 A. I met Russ Soma. I've talked with --
19 met him at a -- do I know -- yes. Russ Soma.

20 Q. Just Russ?

21 A. Just Russ.

22 Q. Did you refer the plaintiffs' lawyers
23 to Russ?

24 A. Yes, I did.

25 Q. Have you ever read an article written

1 by one of the plaintiffs' experts named James
2 Farley?

3 A. No. I don't know the name. But I've
4 heard the name. That's all. I haven't read
5 anything.

6 Q. He wrote an article. And I thought I
7 had extra copies of it here. Let me just read you
8 this, and you can tell me whether you agree with it.

9 He co-wrote this article with a lawyer
10 about discovering the cause of a drug's defect. And
11 it says: "Pre-filing investigation. When a client
12 comes to you suspecting that he or she has taken an
13 adulterated drug, you should tell the client to save
14 the drug, the container and all labeling and
15 packaging information."

16 Here's what I want to ask you about.
17 It says: "Next, a laboratory must analyze the drug
18 and test for its active pharmaceutical ingredient
19 and for strength and purity."

20 Do you agree with that statement?

21 A. That they must or they should? I guess
22 I --

23 Q. It says here "must."

24 A. I would say they should. Because it
25 depends upon the sample and the condition of the

1 sample and...

2 Q. Let's go to Exhibit 29.

3 (Exhibit 29, FDA Collection Report for
4 Sample Number 452746, was marked for
5 identification.)

6 Q. I assume you haven't seen this one
7 either.

8 A. Correct. Yeah, we can assume I haven't
9 seen any of these that look like this form.

10 Q. Okay. And here, we are looking at
11 Sample 462746; correct?

12 A. Correct.

13 Q. Collected March 21, 2008.
14 Is that right?

15 A. Collected when?

16 Q. March 21, 2008.

17 A. March 26, 2008. Correct.

18 Q. And --

19 MR. KAPLAN: I think you were talking
20 over each other. March 21, March 26.

21 A. It says March 26.

22 Q. All right. That's fine. And this is
23 Batch 70834 A?

24 Oh, I'm sorry. Batch 70300 A.

25 Do you find that anywhere?

1 A. I'm trying.

2 I see 56008 A.

3 Q. Do you see a different manufacturer's
4 batch number than I just read?

5 A. Look at this. It appears that that is
6 the lot number.

7 MR. MILLER: And for the record, when
8 you say "this," perhaps we ought to --

9 THE WITNESS: Exhibit 29.

10 MR. MILLER: There was a lot number --

11 THE WITNESS: Yeah.

12 MR. MILLER: -- that you were referring
13 to, I believe?

14 THE WITNESS: The only thing that looks
15 like a -- looks like a lot number is 56008 A.

16 Q. All right. Look on the third page.

17 A. The third page.

18 Q. The middle says Lot 7P964.

19 A. Yes, it does.

20 Q. You see that?

21 A. Correct.

22 Q. And I will represent to you that that
23 is Actavis Batch 70300 A, renumbered by UDL, which
24 made these blister packages, as 7P964.

25 A. Which is not unusual.

1 Q. All right. And FDA tested the same
2 things, identity, content uniformity and assay, and
3 all these specimens passed USP standards?

4 A. Meets specs. That's correct.

5 Q. Do you have any evidence to indicate
6 that there are tablets from Batch 70300 A that do
7 not meet the USP specifications?

8 A. No. I have no evidence.

9 (Exhibit 30, FDA Collection Report for
10 Sample Number 462753, was marked for
11 identification.)

12 Q. Here is Exhibit 30.

13 Is this another FDA 484 sample report?

14 A. Correct.

15 Q. Sample 462753, also collected March
16 2008.

17 A. 2008? I'm sorry. Would you repeat the
18 lot number?

19 Q. I haven't said the lot number. I said
20 the sample number and when it was collected.

21 A. Correct. That is correct.

22 Q. And my notes indicate that that's from
23 Batch 70834 A.

24 A. This has another, I guess, 8A332 on
25 this page.

1 Q. I want you to assume that it is Actavis
2 Batch 70834 A.

3 A. Surely.

4 Q. Did this -- did the specimens tested by
5 the FDA meet the specifications for identification,
6 dissolution and content uniformity?

7 A. On page 1 of 1, the fourth page, it
8 states that: "Lab Conclusion: Meets specs for
9 identification, dissolution and content uniformity."

10 Q. Do you have any evidence to indicate
11 that tablets from Batch 70834 A did not meet those
12 specifications?

13 A. I have no evidence.

14 Q. Are you aware of any occasion in which
15 FDA did a 484 sample and found Digitek that didn't
16 meet the specifications under the USP?

17 A. I have found no exceptions.

18 Q. And I want to go through these quickly,
19 because we -- I will represent to you that the older
20 FDA has these documents, the less weighty they
21 become.

22 (Exhibit 31, FDA Summary Report for
23 Sample Number, was marked for identification.)

24 Q. So Exhibit 31 is another 484 sample
25 set; correct?

1 A. Correct.

2 Q. And it says here that this was Batch --
3 well, this was -- this sample was taken in 2002;
4 correct?

5 A. 2002. March 25th.

6 Q. All right. And it passed the USP
7 requirements for dissolution?

8 A. Correct. "Meets USP uniformity of
9 dosage units spec."

10 Q. And then lower, it says it meets the
11 dissolution specs?

12 A. "Product meets USP requirements for
13 dissolution at Stage 1."

14 Q. All right.

15 (Exhibit 32, FDA Summary Report for
16 Sample Number 157504, was marked for
17 identification.)

18 Q. Exhibit 32 is another Form 484 from the
19 FDA for a sample also taken in 2002; correct?

20 A. Yes.

21 Q. Did the -- did the product, as tested
22 by FDA, meet the USP specs?

23 A. Yes, it did.

24 (Exhibit 33, FDA Summary Report for
25 Sample Number 178890, was marked for

1 identification.)

2 Q. Exhibit 33. Is Exhibit 33 another 484
3 from the FDA?

4 A. Yes.

5 Q. Does it indicate that they took a
6 Digitek sample in 2002?

7 A. Yes.

8 Q. And it passed?

9 A. They have conclusion --

10 Q. Actually --

11 A. It doesn't say anything.

12 Q. Okay. If it didn't -- well, here on
13 the right, it says "In Compliance," does it not?

14 A. I don't know what that means.

15 Q. All right. If -- if it was found to be
16 out of spec, you would have expected to see some
17 evidence of that?

18 A. I would -- I would presume that. I
19 think it's a fair assumption.

20 Q. And the last one of these is
21 Exhibit 34.

22 (Exhibit 34, FDA Summary Report for
23 Sample Number 178891, was marked for
24 identification.)

25 Q. Is this another Form 484 from the FDA?

1 A. Oh, yes. I'm sorry.

2 Q. And tested Digitek?

3 A. Correct.

4 Q. And like the last one we looked at, it
5 says "In Compliance" in two different places?

6 A. Yes.

7 Q. Do you see any evidence that it didn't
8 pass?

9 A. I see no evidence. It's in compliance.

10 Q. At least in the eyes of the FDA, do you
11 believe that these kind of 484 results provide some
12 assurance to them that the product itself is meeting
13 its labeled specifications?

14 A. I would say that all testing that meets
15 specification provides added information, yes.

16 Q. Well, I asked whether it provided FDA
17 assurances that the product was meeting
18 specifications.

19 A. It provides a certain level of
20 assurance.

21 Q. Does it also provide some level of
22 assurance to FDA that its tests are corroborating
23 the finished product tests performed by Actavis on
24 these batches?

25 A. If I make the assumption that Actavis

1 test results are acceptable, then I would say your
2 statement is correct.

3 Q. All right. You looked at the annual
4 reports --

5 A. Correct.

6 Q. -- did you not?

7 A. Yes, I did.

8 Q. Did you find any instances of finished
9 product, either assay or content uniformity, that
10 were outside the specifications, the USP
11 specifications, in the annual reports that you
12 reviewed?

13 A. I'd have to go back to the annual
14 reports to say.

15 Q. Okay.

16 A. Which I have available, if you would
17 like me to.

18 Q. First of all, if they were out of spec,
19 would you have expected there to be investigations?

20 A. Most certainly.

21 Q. Would you have expected there to be FDA
22 regulatory inquiries?

23 A. Not necessarily.

24 They do sampling. They don't -- they
25 don't do a comprehensive review of every annual

1 product review and every batch record. They do a
2 sampling.

3 Q. Okay. Well, in your report, did you
4 note anywhere that there were out-of-specification
5 finished product test results contained in any
6 annual reports?

7 A. I'd have to do more research on Lots
8 80224 A1 and 80227 and 80228 A1, because there's
9 some records indicating that these batches were not
10 acceptable. They had high weights. Both of -- all
11 three of those batches, according to records, says
12 it has high weights. I have not seen the batch
13 records.

14 Q. Do you know how many of those batches
15 were rejected and not sent to Mylan for
16 distribution?

17 A. I would assume that none of the
18 rejected batches were sent to Mylan.

19 Q. Well, do you know specifically of those
20 three how many of them were rejected?

21 A. No. I'd have to go back through the
22 records.

23 I am going to make the assumption that
24 they were rejected. I think that's a fair
25 assumption. The company is not going to release

1 based upon out-of-specification results to the
2 market.

3 I mean, I don't know if that's a fair
4 assumption, but I'm going to assume they --

5 Q. Well, let me get back to my -- my
6 question.

7 Did you note -- did you make comments
8 in your report, which is long -- I mean, 35-some-odd
9 pages -- about any out-of-specification results on
10 batches that were sent to the market for finished
11 product testing?

12 A. That was sent to the market?

13 I'd have to -- I'd have to go back
14 through the history of these batches to see if they
15 were released. I can -- I can think of no example
16 at this particular point.

17 MR. KAPLAN: Again, I'm going to move
18 to strike his last answer as not responsive.

19 He said in your report, did you make
20 any comments?

21 A. Oh, in my report? Well --

22 MR. KAPLAN: No. In your report, did
23 you make any comment on any out-of-spec batches that
24 were sent to the market? Did you? Yes or no?

25 A. I can't answer it that way.

1 Did I make a remark? No. But I can't
2 tell you, without investigating these three batches,
3 whether they went to the market.

4 Q. Okay. Now, we've looked at all these
5 testing by FDA. All right?

6 A. Yes.

7 Q. And let's just take the batches that
8 FDA tested.

9 A. Okay.

10 Q. All right?

11 A. Yes.

12 Q. Just those.

13 If somebody assumed that all of the
14 tablets in a particular batch were outside the USP
15 specifications, this FDA testing proves that that is
16 an incorrect assumption.

17 Is that right?

18 A. That is correct.

19 MR. MORIARTY: I need to look for an
20 exhibit.

21 Q. I'll give you the flattest one.

22 This is Exhibit 35.

23 (Exhibit 35, Celsis Report, was for
24 identification.)

25 Q. Do you see that?

1 A. Yes.

2 Q. This is captioned, on the first page,
3 "Celsis," C-E-L-S-I-S, "Analytical Services."

4 Do you see that?

5 A. Yes.

6 Q. Are you familiar with Celsis Analytical
7 Services?

8 A. No, I'm not.

9 Q. Have you reviewed Exhibit 35? Is it
10 listed in your --

11 A. No.

12 Q. -- Appendix B?

13 A. I have not reviewed it. It is not
14 listed.

15 Q. In the depositions of the Mylan or UDL
16 employees that you read, did you see that, from time
17 to time, UDL sent product out for USP testing?

18 A. Yes.

19 Q. And, on some occasions, they did that
20 just to -- for example, because when they repackage,
21 they need to test dissolution and whether their
22 repackaging is going to affect the stability of the
23 product; correct?

24 A. I don't know why they sent it to UDL.

25 Q. All right. Did you see an instance in,

1 say, any of the Mylan depositions where UDL sent
2 material out to be tested because FDA was concerned
3 about product quality?

4 A. Not specifically.

5 Q. Well, I will represent to you that
6 Exhibit 35, which is rather thick, contains testing
7 done at the behest of UDL, sent to Celsis
8 laboratories on a number of different occasions.
9 And in each instance, the Digitek they sent passed
10 the tests to which it was subjected.

11 Do you have any reason to believe that
12 that did not happen?

13 A. I have no reason to believe, but I'd
14 like to read it in order to answer that, if it's
15 okay.

16 I'm not going to -- I just want to read
17 something.

18 Q. Go ahead.

19 A. Can I write on this?

20 Q. Yes. We have extras.

21 A. It may be a question mark or something
22 like that.

23 I can't read this. It says: "No less
24 than 60 percent in 30," and they scribbled out
25 "percent."

1 In order to confirm this, I'd have to
2 go to the product specification that this is the
3 correct specification.

4 Q. You mean 90 to 110 percent?

5 A. No. I'm assuming that's correct.
6 That's typical, but not necessarily correct.

7 Q. Well, let -- let me rephrase it,
8 because this is a very long document.

9 At any point in the Mylan employee
10 depositions, did anybody bring to the attention of
11 those Mylan employees who were being questioned
12 out-of-specification Digitek results from any
13 testing that UDL had sent to Celsis laboratories?

14 A. I -- I don't know, but I don't recall
15 seeing anything.

16 MR. KAPLAN: Would you read back the
17 last question and answer, please.

18 (Requested portion is read.)

19 Q. Okay. Let's shift to Exhibit 69.

20 (Exhibit 69, UDL Laboratories Receiving
21 Form, was marked for identification.)

22 A. Okay.

23 Q. Have you ever seen Exhibit 69 before?

24 A. It does not look familiar.

25 Q. And attached to all this is documents

1 regarding a shipment of Digitek that was sent to UDL
2 by Mylan and originally by Actavis; correct?

3 A. Yeah. I apologize. I was looking at
4 the specification here of 90 to 105.

5 But could you repeat the question?

6 Q. Well, the documents have to do with a
7 batch of Digitek that was sent to UDL; correct?

8 A. No. But I thought I saw here between
9 90 and 100 is the spec and -- oh, 110. And here,
10 I'm seeing the 90 to 105.

11 Q. Okay. Could there be different specs
12 for different tests?

13 A. Not for assay.

14 But it could be different products.
15 This is .25.

16 May I look at the other document?

17 MR. MILLER: Certainly.

18 THE WITNESS: That one. I think it's
19 on top.

20 A. These are .25, and it says 90 to 110.

21 This is .25, and it says 90 to 105.

22 Q. Do you know whether -- go ahead.

23 A. So one is incorrect.

24 Q. Do you know whether FDA ever changed or
25 USP ever changed the testing specs?

1 A. I don't know, but it's highly unusual.

2 Q. Have you ever seen any Celsis
3 laboratory or UDL documents which indicate that
4 Digitek samples tested by Celsis were ever out of
5 specification, according to the USP specs?

6 A. I don't recall seeing anything.

7 Q. All right.

8 Do you have an opinion as to whether or
9 not any consumer ever received a tablet that was
10 outside -- let me rephrase that. Let me withdraw it
11 and rephrase it.

12 Do you have an opinion, to a reasonable
13 degree of probability, as to whether any consumer
14 ever received a tablet of recalled Digitek that was
15 normal in size but outside its USP specifications?

16 A. Do I have a concern? Yes.

17 Q. That's not what I asked.

18 A. You have to rephrase it.

19 Q. Let's stop. This is a very specific
20 question.

21 A. Sure.

22 Q. Do you have --

23 A. I'm trying to answer it as well as I
24 can.

25 MR. KAPLAN: Listen. Just listen to

1 his question.

2 Q. It's a very specific question.

3 Do you have an opinion, to a reasonable
4 degree of probability, as to whether any consumer
5 received a Digitek -- recalled Digitek tablet that
6 was normal in size but outside its USP
7 specifications?

8 A. Not within a reasonable probability.

9 Q. All right. Are you a -- do you have
10 any expertise in statistics?

11 A. I have knowledge of it.

12 Q. Do you have expertise in it?

13 A. No. I would not say I'm an expert.

14 Q. Do you know anything about statistical
15 significance?

16 A. I have some knowledge of it.

17 Q. All right. Do you have an opinion as
18 to whether 4 1/2 percent -- let me rephrase that
19 question.

20 FDA tested 7 of the 152 recalled
21 batches --

22 A. Okay.

23 Q. -- independently in these 484s that I
24 have had marked as exhibits.

25 By my math, that's 4.6 percent.

1 A. Okay.

2 Q. Okay?

3 Is their testing statistically
4 significant?

5 A. I don't know without taking a look at a
6 statistical table.

7 I will say that it appears like a -- a
8 sample that had a 95 percent confidence interval
9 would approach what would be considered a
10 statistically significant sampling.

11 Q. All right. Celsis labs, by --

12 A. But I would have to pull 105E, or
13 whatever.

14 Q. What's 105E?

15 A. It is a military standard that's used
16 throughout industry for sample -- sample
17 inspections.

18 Q. You mean the one that nobody can read
19 and understand?

20 A. No. I can read and understand it.

21 Q. You may be the only person on earth.
22 Have you used 105E in your work?

23 A. Yes. Not recently, but yes.

24 Q. Is it reliable or considered to be
25 reliable?

1 A. It's considered to be statistically
2 accurate, yes.

3 Q. Okay. Celsis, by my calculations --
4 please assume I'm correct -- independently tested at
5 UDL's request what turned out to be 11 out of the
6 152 recalled batches.

7 A. Okay.

8 Q. Which is 7.2 percent.

9 A. Okay.

10 Q. Is that statistically significant?

11 A. I don't know. I would have to take a
12 look at the tables. It does approach the number
13 that I would anticipate would be in 105E.

14 I'm not trying to avoid it, but I don't
15 know that number. I'd have to take a look at --

16 Q. That's fine. I understand. I told you
17 early on if you don't know the answer to my
18 question, I want you to tell me you don't know.

19 A. I don't know.

20 Q. I don't want you to guess.

21 A. I don't know.

22 Q. Now, if we eliminate any overlap
23 between FDA testing and Celsis testing -- let's
24 assume that that is 16 of the 152 recalled batches.

25 A. Um-hum.

1 Q. Which is about 10.5 percent.

2 Okay? You with me?

3 A. Yes.

4 Q. That would be statistically
5 significant, wouldn't it?

6 MR. MILLER: Object to form.

7 Go ahead. You can answer.

8 A. 105E, all sampling is intended to be a
9 proactive sampling. It is intended to take a look
10 at a distribution of homogeneous product.

11 Based upon the sampling, based upon
12 your acceptability, your AQL, you determine what the
13 sample size is.

14 So, basically, it goes down to how many
15 samples are you willing to say are unacceptable
16 in -- in whatever sampling population you did?

17 You don't back into it by taking
18 samples and keep your fingers -- keep sampling until
19 you find something that's potentially rejectable.

20 That's not a statistical sample. A
21 statistical sample is a proactive, is an
22 experimental plan, and it's based upon probability
23 charts.

24 Q. Were the Amide and then Actavis blend
25 uniformity sampling plans contained in the ANDA?

1 A. I don't know. I'd have to look at the
2 ANDA.

3 Q. Were they contained in every batch
4 record?

5 A. Could you repeat the question?

6 Q. Were they contained in every batch
7 record?

8 A. What --

9 Q. One uniformity sampling plans.

10 A. One uniformity sampling plans, were
11 they contained in -- in the batch records? That's
12 correct.

13 Q. So the number they took and where in
14 the blender, etcetera; correct?

15 A. Yeah.

16 Q. All right. Now, so FDA had every
17 opportunity to comment on those in their analysis of
18 the ANDA or if they ever looked at batch records;
19 correct?

20 A. Yes.

21 Q. And Quantic Regulatory Services had
22 that same opportunity, at least as to the 39 Digitek
23 batches they reviewed; correct?

24 A. That's correct.

25 Q. All right. Now, I don't want to talk

1 about blend uniformity out of specs. I just want to
2 talk about the sampling plan.

3 Have you seen any evidence in any FDA
4 document in which the FDA observed, cited or warned
5 Actavis about the sampling plan itself for blend
6 uniformity?

7 A. FDA? No. I saw nothing.

8 Q. Okay. Now, you know that during batch
9 production of solid oral dose, operators in QA were
10 taking a certain number of tablets for thickness,
11 hardness, appearance and weight; correct?

12 A. That's correct.

13 Q. And those sampling plans were in the
14 ANDA and every batch record; correct?

15 A. They are in the batch record. I'm not
16 sure if it's in the ANDA.

17 Q. And did you ever see, in any FDA
18 document, where FDA observed, criticized or warned
19 Actavis or Amide about the number of tablets that
20 they sampled in that manner in process?

21 A. I don't recall.

22 Q. And then lastly, and then we have to
23 stop to change the tape, the finished product
24 testing, you know, how many they take for content
25 uniformity, how many they take for assay, etcetera,

1 was all in the ANDA and the batch records; correct?

2 A. It's in the batch records.

3 I can't tell you what's in the ANDA.

4 Q. Did you ever see any FDA criticism in
5 any of the documents that you reviewed of the number
6 of samples that Actavis took to test assay or
7 content uniformity or dissolution or stability in --

8 A. In the sampling, no, I did not.

9 MR. MORIARTY: Let's take a break
10 because of the timing.

11 THE VIDEOGRAPHER: Stand by. We are
12 going off the record. The time is 11:29 A.M. This
13 is the end of Tape Number 2.

14 (Recess was taken.)

15 THE VIDEOGRAPHER: We are back on the
16 record. The time is 11:35 A.M. This is the
17 beginning of Tape Number 3.

18 Q. Before that short break, we were
19 talking about sampling plans.

20 First of all, have you referred to any
21 literature in your Appendix B about sampling plans?

22 A. I don't recall. I don't think so.

23 Q. And I don't recall seeing anything in
24 your report critical of my client's in process or
25 finished processed sampling plans.

1 Is that correct?

2 A. Not 100 percent correct.

3 Q. Why not?

4 A. I put in -- I put in there, or I put in
5 the report that as part of issues, non-conformances,
6 out of specifications, situations where high risk
7 could occur, I saw no evidence that they attempted
8 to take a look at the sampling plan to increase the
9 confidence that the product leaving the door didn't
10 have problems.

11 Q. In your opinion, to a reasonable
12 probability, are any of my client's blend
13 uniformity, in process or finished processed
14 sampling plans negligent?

15 MS. CARTER: Objection to form.

16 Q. For Digitek. For Digitek.

17 A. I would say their proactive plans, I
18 saw no -- no issues. I think they were valid
19 sampling plans.

20 Q. All right. I forgot these before when
21 I was asking you about the FDA and their testing of
22 Digitek.

23 Do you know what the batch
24 certification program was way back when, in the '80s
25 and '90s?

1 A. I heard the term. I'm not familiar
2 with it.

3 Q. That's when, for some drugs, FDA had to
4 test and approve the release of batches before they
5 could go to market; correct?

6 A. I don't know if that's correct.
7 (Exhibit 4, Letter dated June 8, 1995
8 to Shah from Department of Health & Human Services,
9 was marked for identification.)

10 Q. Have you ever seen Exhibit 4?

11 A. No, I have not. 1995?

12 Q. This is a letter from FDA to then Amide
13 indicating that these nine batches of Digitek passed
14 their testing and could be released to market;
15 correct?

16 A. That's correct. This 1995 document,
17 yes.

18 (Exhibit 5, Letter dated July 20, 1995
19 to Shah from Department of Health & Human Services,
20 was marked for identification.)

21 Q. And here is Exhibit 5. Is this a
22 letter -- first of all, have you ever seen this
23 before?

24 A. No, I have not.

25 Q. Is this a letter from FDA to then Amide

1 indicating that they were exempt from the batch
2 certification program?

3 A. That's what it states.

4 Q. And wouldn't FDA only do that if they
5 had a high degree of confidence that the process was
6 validated and in control?

7 A. I believe that's correct.

8 Q. Okay. Do you know how many people in
9 the United States were prescribed Digoxin between
10 2006 and 2008?

11 A. No. I have no idea.

12 Q. Do you know how many prescriptions were
13 written for Digoxin products between 2006 and 2008?

14 A. I have no idea.

15 Q. Do you know how many people were taking
16 Digitek between 2006 and 2008?

17 A. I have no idea.

18 Q. Have you ever done the math to figure
19 out how many tablets were affected by the Digitek
20 recall?

21 A. How many tablets were affected? No, I
22 have not.

23 If you figure there's 5 million
24 tablets, and go through the number of lots, and
25 multiply it out --

1 Q. It would be --

2 A. -- millions.

3 Q. -- about 688.2 million.

4 A. Okay.

5 Q. Approximately. Is that correct?

6 A. If you say so. You've done the math.

7 Q. If you go by the theoretical batch size
8 of 4.8 or 4.2.

9 A. Okay.

10 Q. Correct? Depending on the dose size?

11 A. If your math is right. And I have no
12 reason to believe it's not.

13 (Exhibit 36, Recall -- Firm Press
14 Release, was marked for identification.)

15 Q. This is Exhibit 36.

16 I believe you've seen this.

17 That's in your --

18 A. Yes.

19 Q. -- binder, isn't it?

20 That's the recall press release?

21 A. Well, it might not be in my binder
22 because I looked at it electronically.

23 Q. Is it the recall press release?

24 MR. KAPLAN: Is there an answer to that
25 question?

1 THE WITNESS: I'm briefly looking
2 through it.

3 MR. KAPLAN: The question is simply:
4 Is that the recall press release?

5 THE WITNESS: This is a -- yes. Yes.
6 It appears to be, yes.

7 Q. And it's Tab -- or it's Reference
8 Number 59 in your Appendix B, is it not?

9 A. Yes.

10 Q. Now, it indicates generally in here
11 that the recall is due to the possibility that
12 tablets with double the appropriate thickness may
13 have been commercially released.

14 Do you see that?

15 A. Yes.

16 Q. Is there anywhere in Exhibit 36 that
17 indicates that this recall was about tablets of
18 normal size with varying levels of deactive
19 pharmaceutical ingredient?

20 A. Well, yes. Double strength. It varies
21 by two.

22 Q. Let's -- let's read that again and ask
23 my question again.

24 It says: "The voluntary all-lot recall
25 is due to the possibility that tablets with double

1 the appropriate thickness may have been commercially
2 released."

3 Do you see that?

4 A. Yes.

5 Q. My question is this: Is there anything
6 in this FDA-approved press release that indicates
7 that this recall was about normally-sized tablets
8 with varying levels of the active pharmaceutical
9 ingredient?

10 A. Normal size, no.

11 Q. All right. In your opinion, Mr. Kenny,
12 is double thick a different problem than normal size
13 with varying active pharmaceutical ingredient?

14 A. Could you repeat the question again?
15 I'm trying to answer that clearly.

16 Q. Sure. You were in the pharmaceutical
17 business with J&J for 30 years; right?

18 A. Yeah. On and off.

19 Q. Okay. You know what investigations are
20 all about; correct?

21 A. Most certainly.

22 Q. And you know generally how to
23 manufacture, blend manufacture tablets?

24 A. In general, correct.

25 Q. All right. If somebody came to you,

1 either at J&J or now in your consulting work with
2 SpyGlass, and said we've got a problem with
3 double-thick tablets, you would design an
4 investigation about that; correct?

5 A. I would assist them, if asked.

6 Q. Okay. And I assume that what you're
7 looking for is some sort of a cause --

8 A. Correct.

9 Q. -- of what would make double-thick
10 tablets; right?

11 A. Right.

12 Q. And, obviously, it's a size issue. At
13 its core, it's a size issue; correct?

14 A. There is a -- it's -- I guess I would
15 say yes.

16 Q. All right. And then, by virtue of
17 size, you'd want to know what -- is it too many
18 excipients with normal pharmaceutical ingredient
19 levels, or is it double the active pharmaceutical
20 ingredients; right?

21 A. Right. You'd want to know the --
22 whether or not the content uniformity was correct.

23 Q. Right.

24 A. And if you made -- did an investigation
25 and said content uniformity is correct, then it

1 would probably pinpoint you to a tableting press,
2 and you'd say that it is a physical issue.

3 Q. All right. Now, but on the other side
4 of the equation, if somebody at J&J or in your
5 consulting business with SpyGlass said we have a
6 problem with -- our tablets are normal in size, but
7 the active pharmaceutical ingredient is varying all
8 over the place, your investigation would potentially
9 take a different course; correct?

10 A. Of course.

11 Q. And the root cause might be completely
12 different from the first scenario; correct?

13 A. It is a possibility it could be
14 completely different, yes.

15 Q. And that is a distinction that the FDA
16 would clearly recognize; is it not?

17 A. I don't know. I can't speak for them.

18 Q. Have you seen any document to indicate
19 that the Digitek recall was about anything other
20 than the double-thick tablet investigation that grew
21 out of Batch 70924 A?

22 A. Stated as such, no.

23 (Exhibit 38, FDA Website Statement July
24 2009, was marked for identification.)

25 Q. I've handed you what's been marked as

1 Exhibit 38; correct?

2 A. Correct.

3 Q. Have you ever seen that before?

4 A. Yes, I have.

5 Q. This is a statement on an FDA website
6 from July of 2009.

7 Is that right?

8 A. Where do you see 2009?

9 You printed it on 6/15/2010.

10 Q. Which means it's still on the FDA
11 website this month; correct?

12 A. I believe that.

13 Q. Do you know when they initially posted
14 this?

15 A. I have no idea.

16 Q. And it's a -- it's entitled "Facts and
17 Myths About Generic Drugs."

18 Do you see that?

19 A. I certainly do.

20 Q. And down about halfway on the first
21 page of this exhibit, it says: "Recently, some
22 misinformation has raised concerns over generic
23 drugs. Below are some common myths in circulation."

24 Did I read that correctly?

25 A. Halfway down? Please show me.

1 Q. There or there.

2 A. "Recently, some misinformation" -- yes.

3 "Below are some of the common myths in circulation."

4 Q. Go to the second page, please.

5 The first full section on the second
6 page says: "Myth: There are quality problems with
7 generic drug manufacturing. A recent recall of
8 generic Digoxin, called Digitek, shows that generic
9 drugs put patients at risk."

10 Did I read the myth correctly?

11 A. I believe you did.

12 Q. And then it says: "Fact: FDA's
13 aggressive action in this case demonstrates the high
14 standards to which all prescription drugs, generic
15 and brand name, are held."

16 Did I read that correctly?

17 A. Yes, you did.

18 Q. Now, let's go down to the fourth bullet
19 point, the second sentence in the fourth bullet
20 point.

21 "In our best judgment, given the very
22 small number of defective tablets that may have
23 reached the market and the lack of reported adverse
24 events before the recall, harm to patients was very
25 unlikely."

1 Did I read it correctly?

2 A. Yes, you did.

3 Q. Do you disagree with the FDA's
4 statement in this website?

5 A. Yes, I do.

6 Q. What's your basis for disagreeing with
7 the FDA's conclusion in this regard?

8 A. Okay. There is, at least in my
9 industry, a generally-accepted term, or at least
10 concept, that you only receive a small portion of
11 the actual adverse reactions, general complaints,
12 regardless; that either the people don't realize
13 that they had a problem, they're lazy, so that
14 people have quoted 1 in 20 people will actually
15 complain.

16 On consumer products, it could be
17 slightly higher. There's an 800 number they call up
18 and get a free product.

19 People don't even understand how to
20 complain, if you will.

21 So I would not agree with that
22 statement.

23 Q. So the part that you're focusing in on
24 is what the FDA said here about the lack of reported
25 adverse events before the recall?

1 A. Correct.

2 Q. When you were with J&J, were you in
3 pharmacovigilance?

4 A. No.

5 Q. Are you a pharmacovigilance expert?

6 A. I am not.

7 Q. When you consult for SpyGlass to your
8 current clients in the last six years, do you
9 consult in pharmacovigilance?

10 A. I -- I consult indirectly to that.
11 I look at complaints. I look at
12 adverse events. I look to the investigations that
13 they performed. I determine whether or not their
14 investigations are adequate.

15 I make a clear determination, based
16 upon looking at, over the -- just the last year,
17 hundreds of adverse reactions and complaints as to
18 whether or not I felt, in my opinion, they were
19 adequately investigated.

20 So I will tell you, as part of the
21 pharmacovigilance process, that is my role I've been
22 asked to perform.

23 Q. Have you seen any evidence in this case
24 that there were reports of harm to Actavis regarding
25 Digitek prior to the recall that were not reported

1 to the FDA at all?

2 A. I have seen no evidence in that regard
3 at all. I haven't seen any reports of adverse
4 events. I have seen no complaint investigations,
5 other than 3611A.

6 So I -- I can't answer that because I
7 haven't seen anything.

8 Q. All right. Let me break the FDA's
9 website statement down in phrases.

10 A. Okay.

11 Q. They say: "In our best judgment, given
12 the very small number of defective tablets that may
13 have reached the market."

14 Do you agree with them when they make
15 that statement?

16 A. I don't know how they can say the
17 number is very small. They don't know.

18 Q. And you don't know either, do you?

19 A. Of course not.

20 Q. Okay.

21 A. But if somebody makes a determination
22 that's counter to my experience, I can't make
23 that -- say the number is very small. I can't say
24 there's none. I can't say that there are a lot.

25 I think, based upon this type of -- in

1 this context, you know, I'm not trying to be
2 difficult, but I couldn't say that.

3 Q. All right. The last statement that
4 they make, "harm to patients was very unlikely," do
5 you agree with that?

6 A. I have -- this is clearly going beyond
7 my own expertise.

8 Q. Well, just statistically, if you don't
9 know the number of defective tablets that may have
10 gotten out, you have no way to quantitate the
11 potential harm to consumers, do you?

12 A. I am not involved in harm to consumers.
13 I'm involved with the manufacturing process. I'm
14 involved at the compliance level. I'm involved with
15 adequate investigations. I'm involved with annual
16 product reviews. That's the extent.

17 Anything -- if I start going into the
18 field and determine whether something's safe or not,
19 I've gone beyond my own expertise. And that would
20 be irresponsible.

21 Q. Do you have any idea what percentage of
22 pharmacies still hand-count out tablets when they
23 fill prescriptions?

24 A. I have no -- no idea.

25 Q. Do you have any opinion, from a

1 pharmacy point of view, as to how easy it would be,
2 relatively speaking, to detect a double-thick
3 Digitek tablet?

4 MR. MILLER: Object to form.

5 A. I would have no idea.

6 Q. If you wanted to scientifically
7 determine whether double-thick tablets -- let's just
8 leave it at that for now -- ever actually got to
9 consumers, would you look at batch records about the
10 weighing and measuring of tablets?

11 A. Most certainly.

12 Q. Would you ask consumers to have their
13 tablets weighed or measured?

14 A. Ask consumers? I don't believe so.

15 Q. Okay.

16 A. Let me answer that accurately. What do
17 you mean by "ask consumers"? I am not involved with
18 asking consumers.

19 Q. That's fine. We're in the context of a
20 litigation --

21 A. Okay.

22 Q. -- where the population on one side is
23 a discrete number of people who claim they got
24 defective tablets. Let's continue to stick with
25 double thick.

1 A. Okay.

2 Q. Among the people who still had tablets
3 left over, the weighing and measuring of them with
4 micrometers and sensitive scales is not a difficult
5 process, is it?

6 A. Weighing -- no.

7 Q. And if you wanted to investigate, like
8 Professor Farley's article said, weighing and
9 measuring could be done; correct?

10 A. Yes.

11 Q. And you would want to look to the
12 instances of customer complaints made to either the
13 distributor or to Actavis itself about double-thick
14 tablets found by consumers, would you not?

15 A. I would look at that and other
16 potentially related adverse events and -- I would
17 look at the entire picture. I would not just limit
18 it to this one situation, because it could be -- it
19 could be a compounded -- a confounded issue based
20 upon things that I don't know.

21 So you look at everything because you
22 don't know what you don't know.

23 Q. Okay. Well, let me ask: First, with
24 regard to recalled Digitek, have you ever seen
25 anything in any of the material that you reviewed

1 that a pharmacist or a consumer has reported an
2 actual tablet that is outside its size or weight
3 specifications?

4 A. I -- I don't believe that I've seen it.

5 Q. Okay. So I've asked you that. An hour
6 or so ago, I asked if you have seen any evidence
7 that there were tablets of normal size with outside
8 the USP specifications for active pharmaceutical
9 ingredient.

10 And you said you hadn't seen any of
11 those either; correct?

12 MR. MILLER: Objection to form.
13 Misstates previous testimony.

14 A. You know, it's interesting, based upon
15 the fact --

16 MR. KAPLAN: Wait, wait.

17 THE WITNESS: I'm sorry.

18 MR. KAPLAN: You started -- you started
19 making a comment. You are not responding to the
20 question. Please refrain from that.

21 THE WITNESS: I want to answer his
22 questions, sir.

23 Q. Have you seen any tests from consumers
24 or otherwise --

25 A. Okay. Are returned samples from

1 consumers?

2 Q. Returned samples from consumers or
3 tests that consumers have of samples that they kept
4 or tests done by the FDA or anybody else to indicate
5 that there are normal-sized tablets outside the
6 specification --

7 A. I haven't seen any tests.

8 Q. Okay.

9 A. So I can't see any tests that are out.

10 Q. All right. So do you have any evidence
11 at all that Digitek, outside its labeled
12 specifications, reached consumers in this
13 litigation?

14 A. Please, this is an important question.
15 Repeat it.

16 MR. MORIARTY: Read that one back,
17 please.

18 (Requested portion is read.)

19 A. I have no evidence.

20 Q. Do you know what a red herring is?

21 A. I think I do.

22 Q. Do you know plaintiffs' lawyers in this
23 litigation said, in court and in court documents,
24 that the double-thick theory is a red herring?

25 MR. MILLER: Object to form.

1 A. I'm not familiar with that.

2 MR. MORIARTY: What was wrong with the
3 form of that question, Pete? Because I'd really
4 like the opportunity to correct it.

5 MR. MILLER: Well, it's vague.

6 What -- what attorneys? He's worked
7 with several attorneys. And it's -- I think the
8 term "attorneys" is broad and vague.

9 If you want to put the who into it.

10 MR. MORIARTY: Your colleagues in the
11 PSC.

12 He said he wasn't aware of it, so I
13 don't need to get more specific.

14 Q. Can you point me to any FDA 483 warning
15 letter or EIR in the material that you reviewed that
16 specifically indicates that they found Digitek
17 tablets of normal size with varying amounts of the
18 active pharmaceutical ingredient?

19 A. That were released?

20 Q. Yes.

21 A. I don't recall any instances.

22 Q. Okay. Can you show me in any of the
23 material you reviewed any statement by the FDA that
24 they found normal-sized Digitek tablets -- okay.
25 I'll withdraw that question.

1 When you say "released," you mean
2 released to a distributor to go to market; correct?

3 A. Once you let -- once you say it's
4 released in your SAP system, it's released, because
5 it's out of your control at that particular point.
6 That's what I mean by "released."

7 Q. Does the ANDA have a section that
8 contains the actual pharmaceutical product formula
9 for Digitek?

10 A. Yes, it does.

11 But I will say I am and most quality
12 assurance people are not experts at the ANDA.

13 What we are, is we are experts once
14 that -- once that -- once -- the ripple effect, if
15 you will, somebody in regulatory and development has
16 taken that and translated it into a specification.
17 When it becomes a specification, then quality
18 assurance people are involved.

19 Q. Okay. But in general, from what you
20 know, is the pharmaceutical formulation, the recipe,
21 if you will, contained in all the batch records?

22 A. In the batch records? Yes, it is.

23 Q. So FDA presumably has had an
24 opportunity to look at the ANDA and all these batch
25 records, if it looks at them, to see what the

1 formula is about; correct?

2 A. I don't know what they looked at.

3 Q. All right. And in order to start the
4 process off right, you have to mix the ingredients
5 appropriately and in their appropriate proportions;
6 correct?

7 A. That is correct.

8 Q. One potential root cause of tablets
9 outside their active pharmaceutical ingredient specs
10 would be if they mixed it wrong initially by putting
11 in either too much or too little API.

12 Is that right?

13 A. Yes.

14 Q. Have you seen in the material that you
15 reviewed any citations, warnings by FDA upon Actavis
16 or Amide for problems related to following the
17 formula appropriately and putting in the proper
18 amount of API?

19 A. I do not recall a single instance.

20 Q. All right. And typically, the actual
21 mixing of the ingredients in its proportions is done
22 by one person and then verified by a second.

23 Is that right?

24 A. That's the way it's supposed to be
25 done. Correct.

1 Q. Did you see any batch record that
2 indicated that the company did not follow the
3 appropriate formula?

4 A. No.

5 Q. If by chance, purely hypothetically,
6 the company wanted to -- any pharmaceutical company
7 wanted to cut corners and save costs, they would put
8 too little API in the batch as opposed to too much;
9 correct?

10 A. Sir, it is illegal to vary from the
11 batch record.

12 If you are assuming that somebody was
13 totally unethical, then they may put that in. I
14 can't speculate on somebody who is totally
15 dishonest.

16 Q. All right. And you've seen nothing in
17 here, in the material you've reviewed, to indicate
18 that anyone at Amide or Actavis was totally
19 dishonest in the manufacturing of Digitek; correct?

20 A. Correct.

21 Q. Are you aware that --

22 A. Can I qualify that?

23 I don't know how I would understand
24 whether they were honest or not.

25 I guess I would say that it's a

1 question that nobody can answer.

2 Q. Okay. Are you aware that in the
3 process of making a solid oral dose, the raw
4 materials are weighed at the beginning of the batch
5 to assure that it complies with the formula?

6 A. That's correct.

7 Q. And then, as you go through the
8 process, after mixing and blending, it's weighed
9 again; correct?

10 A. Correct.

11 Q. And --

12 A. "It," meaning the blend is weighed?

13 Q. Yes. The blend is weighed again.

14 And in the validation process, the
15 company should have figured out how much it is
16 supposed to weigh at various steps along the path.

17 Is that true?

18 A. I wouldn't state it that way, but I
19 think I understand what you're trying to say. I
20 would say it's true.

21 Q. And it's -- in essence, it's a quality
22 control check to make sure that you're not losing
23 too much or gaining anything.

24 Is that right?

25 A. Well, it's not that you're not losing

1 or gaining. It's did you put the correct amount of
2 ingredients in?

3 The issue with that is, if the
4 ingredients are very small, it's kind of like
5 weighing yourself on the Queen Mary.

6 You know, you jump on the Queen Mary,
7 weigh yourself, then you jump off and you weigh the
8 Queen Mary again, and you subtract to determine that
9 you're X number of pounds.

10 So yes, it is -- it is a check that is
11 supposed to provide some evidence that the correct
12 ingredients are there, yes.

13 Q. All right. But let's pick two extreme
14 examples.

15 If somebody tripped and dumped a bucket
16 of screws into a batch, and there was a weight
17 variance, that would provide a potential check for
18 the company to evaluate why does this batch at the
19 blend stage weigh 5 pounds more than it should;
20 right?

21 A. I would say it depends.

22 Q. Okay.

23 A. It depends on -- do you want me to
24 answer?

25 Q. I think you've -- I think you gave me

1 the answer.

2 A. No. I -- it's a different answer.

3 MR. MILLER: Matt, why don't you let
4 him -- why don't you let him give the full answer.

5 MR. MORIARTY: I got the answer I want.

6 MR. MILLER: You got the answer and you
7 cut him off. Okay.

8 Q. At the other end of the -- of the
9 spectrum, if accidentally somebody dumped a certain
10 amount of product down the drain, they could check
11 why the batch at a particular stage of the process
12 was too light; correct?

13 A. They would not necessarily detect it.

14 As I was going to state earlier, there
15 is a range, an acceptable yield range at every
16 single point in the process.

17 If those yield ranges are exceeded,
18 then it is out of specification and an investigation
19 would occur.

20 Q. Okay.

21 A. If -- if the error occurred so that you
22 threw a screw in there, and it didn't increase the
23 weight of the batch any significant amount, and it
24 stayed within the limits, you'd be oblivious to the
25 fact -- perhaps you would find out in the tableting

1 press, but you would be oblivious to it until
2 perhaps a later stage.

3 Q. Sure. But the purpose of these yield
4 calculations is it's a quality check along the way;
5 right?

6 A. It is a gross quality check.

7 Q. There is a lot of weighing and
8 measuring through the whole process; right?

9 A. It's a gross quality check.

10 Q. Okay. And do you think that finished
11 product testing, according to the USP methods, is a
12 gross quality check or something else?

13 A. I -- I wouldn't use the term "gross
14 quality check."

15 I would say it's a very specific test
16 for tablets. It's a very good test method. And it
17 is likely to detect any products that are out of
18 specification.

19 Q. All right. And one of the reasons you
20 do all these checks is to see whether a validated
21 process remains in control.

22 Is that right?

23 A. One of the reasons you do these things
24 meaning what? "These things"?

25 Q. You have a formula, you weigh things,

1 you measure things, you test them for hardness, all
2 along the route. Is that in order to assure that
3 your validated process remains in control?

4 A. It is certainly one of the reasons,
5 yes.

6 Q. Have you ever seen any statement in all
7 the material that you reviewed from FDA to indicate
8 that Digitek manufacturing processes were outside
9 their validated control methods?

10 A. Yes.

11 Q. For Digitek?

12 A. Yeah. I did not look at lot of
13 batches. Yes, with the double-thickness batch. A
14 validated batch cannot produce a double-thick
15 tablet. It is considered invalidated if -- if at
16 end there is the least bit of -- of issue, then you
17 have to assume it is invalidated, is the
18 investigation which goes to the root cause, which
19 then either confirms that it remains a validated
20 state, or, in fact, your investigation determines
21 that there is an issue, and that you don't have a
22 reliable process.

23 Q. All right. So first of all, before
24 Batch 70924, did you see any evidence from FDA that
25 Digitek manufacturing processes were outside their

1 validated control levels?

2 A. I really have to go back to the 43s and
3 the EIRs to answer that. I'm not trying to avoid
4 the question. I -- I would have to do that.

5 Q. Okay. In association with Batch 70924,
6 did the FDA ever explicitly say that, "We believe
7 your validated method is out of control"?

8 MR. MILLER: Object to form.

9 A. Honestly, I'd have to go back to the
10 records to confirm that.

11 Q. All right. Well, what I'm trying to
12 find out is, you just gave me your opinion that
13 70924 indicates an out-of-control process.

14 I want to make sure that that's your
15 opinion, and not something you saw that the FDA
16 said.

17 A. I understand.

18 Did they specifically point to Digitek?
19 I don't recall. I -- I am willing to go back
20 through the records and answer that with, you know,
21 more facts and data.

22 Q. Okay. You can do that at the lunch
23 break, if you wish.

24 A. I'd rather have lunch, but okay.

25 MR. KAPLAN: Well, it is important. I

1 just want to say it's very important for us here
2 today to -- to be able to get your opinions and test
3 your opinions. You know you've issued a 35-page
4 report. I think it's fair for us to assume that
5 you've done all the work that you need to do, you've
6 issued your opinions, now we get to ask you about
7 them.

8 So whatever you need to do to answer
9 our questions, I assume you've done.

10 But if you need to do something during
11 the lunch break, well, please do it.

12 MR. MILLER: It doesn't have to be
13 during the break. You can review documents at any
14 point in time.

15 A. If you -- if you feel it's important
16 enough to get a complete answer on that, I -- I gave
17 my answer. I will gladly go back through it --

18 MR. KAPLAN: We need the truth, the
19 whole truth and nothing but the truth, and this is
20 our only opportunity to examine you.

21 THE WITNESS: Sir, I -- I respect that
22 100 percent. You are getting 100 percent of the
23 truth. You're talking to somebody who does not veer
24 away from the truth. Okay?

25 MR. MILLER: Yeah, that's -- let's wait

1 for a question.

2 THE WITNESS: Okay. Well --

3 MR. MILLER: But if you want to
4 review -- if you want to read the documents, then
5 we --

6 MR. KAPLAN: But when we're told
7 something like, well, I can't answer it because I'd
8 have to do the work all over again, then it's not
9 fair. It's just not fair.

10 MR. MILLER: He didn't say that. He
11 said, I'll have to review the documents. You can
12 certainly put the documents in front of him.

13 MR. MORIARTY: Can I get back to work?

14 THE WITNESS: Yeah. I'm sorry.

15 MR. MORIARTY: Thanks.

16 THE WITNESS: Can I take a bio break?
17 I need a very quick bio break.

18 MR. MILLER: This is a good time for
19 lunch.

20 MR. MORIARTY: Can you hang on for four
21 minutes?

22 THE WITNESS: Four minutes. Okay.

23 Q. If a company -- if a pharmaceutical
24 company consistently put too much active
25 pharmaceutical ingredient into its batches, is it

1 more likely than not that their accounting for raw
2 materials in inventory wouldn't reconcile?

3 A. I can't answer that question. It
4 depends upon the percentage of -- of active that
5 they put in.

6 Again, when they reconcile, there's an
7 acceptable tolerance. The tolerance is based upon
8 the history.

9 If the history is such that you add too
10 much, then it would be -- it would be hidden within
11 those specifications.

12 But, to answer your question again,
13 that is one of the control checks which you have to
14 try to determine whether or not you have misuse --
15 you use too much or too little.

16 Q. Okay. If a pharmaceutical company
17 consistently put so much active pharmaceutical
18 ingredient extra into its batches that they were
19 outside the specifications, would that be something
20 likely would be detected by --

21 A. So you're talking about if they -- if
22 we used hypothetical -- let's say produced a product
23 that was outside of specification which was
24 consistently above 110 percent.

25 Q. Yep.

1 A. Would the --

2 Q. It's actually 105.

3 A. 105. The other one said 110.

4 Q. Trust me.

5 A. Well, I'm not necessarily going to
6 trust you on this, but -- but it's above -- well,
7 105 is harder, so I'll use the 105.

8 Would it be detected in the long run if
9 you --

10 Q. Likely. Would it likely be detected in
11 the long run.

12 A. You know what, without looking at
13 their -- without looking at their yield limits, I
14 don't know how I could make that determination.

15 Q. Would the added Digoxin likely be
16 detected at either blend uniformity or finished
17 product testing?

18 MR. MILLER: Objection to form.

19 A. Just repeat that, please.

20 Q. If the company consistently added such
21 an amount of additional Digoxin that it was going to
22 be outside the specifications, would it likely be
23 detected by blend uniformity or finished product
24 testing?

25 A. Yes, it would, if they have a valid

1 test method.

2 MR. MORIARTY: Let's stop there because
3 I'm going to push beyond four minutes and I don't
4 want to do that to you. And then do you want to
5 just take our lunch break?

6 MR. MILLER: Yes.

7 THE VIDEOGRAPHER: Please stand by. We
8 are going off the record. The time is 12:18 P.M.
9 This is the end of Tape No. 3.

10 (Lunch recess was taken.)

11 THE VIDEOGRAPHER: We are back on the
12 record. The time is 1:37 P.M. This is the
13 beginning of Tape No. 4.

14 Q. All right, Mr. Kenny. Let me do --
15 first start the afternoon with a little bit of
16 cleanups from some things.

17 (Exhibit 22, letter dated 1/9/07,
18 was marked for identification.)

19 Q. And I want to show you what's been
20 marked as Exhibit 22.

21 This is a letter dated January 9, 2007,
22 from FDA to Actavis; correct?

23 A. Correct.

24 Q. It is a warning letter; correct?

25 A. Correct.

1 Q. And if you go to the second to last
2 page, last paragraph, I'd like you to follow along
3 with me.

4 It says, "While the corrections that
5 you promise in your correspondence appear to
6 adequately address many of the cGMP deviations found
7 during the July 10 through August 10, 2006
8 inspection, we are concerned about the quality of
9 drug products that have been released from your
10 facility under the serious lack of cGMP controls
11 found during the inspection."

12 Did I read that correctly so far?

13 A. I believe so.

14 Q. And then I'm going to skip the next
15 sentence -- well, actually, let's go on to the next
16 sentence.

17 "Your response provides no assurance."

18 Now, "provides no assurance" is a
19 frequent term used in FDA regulatory materials;
20 correct?

21 A. Um-hum.

22 Q. That's a yes?

23 A. Yes.

24 Q. "That the records and conditions of
25 manufacture and testing of each such lot of drug

1 products released and marketed will be evaluated to
2 assure that the released drug products have their
3 appropriate identity, strength, quality, and
4 purity."

5 Again, "identity, strength, quality,
6 and purity" are regulatory terms frequently
7 contained in FDA materials; correct?

8 MR. MILLER: Object to form.

9 A. Yes.

10 Q. Now, the next sentence says, "We feel
11 that to provide such assurance, your firm should
12 promptly initiate an audit program by a third-party
13 having appropriate cGMP expertise to provide
14 assurance that all marketed lots of drug products
15 that remain within expiration have their appropriate
16 identity, strength, quality and purity."

17 Did I read that correctly?

18 A. Yes.

19 Q. Do you understand this to be the
20 invitation which led Actavis to retain Quantic
21 Regulatory Services?

22 A. I believe it is the invitation to bring
23 in a consultant, which became Quantic.

24 Q. And we have already gone over the
25 Quantic exhibit. I don't need to discuss that

1 again.

2 But do you know whether FDA ever
3 expressed any dissatisfaction with Quantic's results
4 such that they did not provide assurances that
5 Digitek had been produced under conditions which
6 assured appropriate identity, strength, quality and
7 purity?

8 A. Yeah. I think that the FDA had a high
9 level of concern based upon a complete system issue,
10 not necessarily -- taking a look at each of the
11 quality systems.

12 MR. KAPLAN: I would ask the
13 reporter -- I move to strike that answer as not
14 being responsive.

15 MR. MORIARTY: And I understand your
16 answer, but one --

17 MR. KAPLAN: I'd like the reporter to
18 read back the question that you asked so he can
19 answer that question.

20 MR. MORIARTY: And actually my question
21 was very bad. Your -- your answer wasn't
22 responsive, but my question was pretty bad. Okay?

23 MR. MILLER: I know --

24 MR. MORIARTY: Early on -- early on
25 after lunch, it's difficult to keep going.

1 Q. What I'm asking specifically is whether
2 FDA ever said, "Sorry, Actavis" or "Sorry, Quantic,"
3 the letter you, and results, you provided in
4 December of 2007 don't give us the assurances that
5 we need concerning Digitek.

6 MR. MILLER: Object to form.

7 Q. Anything like that in the material you
8 reviewed?

9 A. I think their actions, the regulatory
10 and escalating of their actions state that they
11 weren't satisfied with their response.

12 Q. Is there an explicit statement anywhere
13 in the materials you reviewed about Digitek, they
14 were not satisfied with Quantic's work in regard to
15 this specific invitation?

16 A. I don't recall.

17 Q. In your Tab 2 -- I'm sorry. Tab -- I'm
18 sorry, Tab 5. Reference 5 in your Appendix B is
19 this definition of adulterated; correct?

20 A. Correct.

21 Q. All right. Well, we -- we printed this
22 from the website, and probably have other copies of
23 it, but this is the specific part about strength,
24 quality and purity differing from official
25 compendium; correct?

1 A. Um-hum.

2 Q. Is that a yes?

3 A. Yes. Sorry, right.

4 Q. And this is CFR 351B; correct?

5 A. Correct.

6 Q. Now, in this paragraph, is that
7 language -- again we're talking about assurances
8 that a product meets identity, purity, strength,
9 etcetera; correct?

10 A. Correct.

11 Q. Now, is there anything in here that
12 defines what an assurance is?

13 A. Can I read it?

14 I don't see that.

15 Q. All right. In other words, there's no
16 statement that -- of confidence intervals or
17 statistical probabilities in any precise
18 mathematical terms; correct?

19 A. Correct.

20 Q. Are the -- are the general -- are the
21 good manufacturing practice regulations subject to
22 varying interpretations from time to time?

23 A. By whom?

24 Q. Well, between a company and the FDA,
25 for example.

1 A. I'm sorry. Would you repeat that?

2 Q. Sure. I mean could two reasonable
3 professionals, even in your field, look at a
4 definition in the GMP guidelines and have a
5 legitimate debate about what a particular word or
6 phrase means?

7 A. Yes, sir.

8 Q. All right. So as far as the word
9 "assurance" is concerned, some expert like you could
10 say, I believe that we, as a company, have provided
11 the adequate assurance; and somebody else on the
12 other side could say, no, I disagree; right?

13 A. That's correct.

14 Q. And at least the FDA reg itself doesn't
15 provide specific guidance on what that means; right?

16 A. In terms of assurance, sure it does.
17 It gives you guidance document and it tells you the
18 minimum requirements, and if you perform the minimum
19 requirements, you have assured, to at least a -- to
20 a legal standpoint that you've assured that the
21 product will meet -- will meet all specifications,
22 etcetera, GMP regulations, and will not be an
23 adulterated product.

24 Q. You mean from a regulatory standpoint.

25 A. I mean they're linked. Whether --

1 whether you're talking about adulterated product
2 meaning total GMP compliance issue, and no spec --
3 and no out of specifications, that's -- let's say
4 that's stated there. But the assurance that they're
5 implying is, also, that the product going out the
6 door is -- is compliant to specifications. So it
7 refers to, I believe, both.

8 Q. But the FDA statement in their July --
9 or their cGMP statement that we went over before
10 doesn't necessarily equate the assurance of
11 regulatory with the actual laboratory outcome of
12 tested product; correct?

13 A. Seriously, I don't understand the
14 question.

15 Q. That's fine.

16 You have expressed opinions in your
17 report that you have -- you believe that Actavis had
18 serious GMP issues in certain years; correct?

19 A. Through the years I had evidence, yes.

20 Q. Okay. At the same time, FDA was
21 testing product in 2007/2008, and it was meeting
22 specifications; correct?

23 A. Correct. It appears, you've shown me a
24 lot of information to suggest that it met
25 specifications.

1 Q. Right. And you've not shown me any
2 evidence in the material you reviewed to the
3 contrary, that it didn't meet specifications;
4 correct?

5 A. Well, we haven't discussed -- you've
6 talked about whether or not a product tests as a
7 final product meets the specifications.

8 Q. Right.

9 A. Yes. When you've asked me that
10 question, I've said yes. I don't have any data for
11 that. But I have data prior to that. I mean,
12 there's -- there's tons of things prior to that that
13 would implicate the quality of that particular
14 product.

15 Q. We'll get to that later.

16 But in the end --

17 A. I mean actual test results.

18 Q. -- if a consumer is going to take a
19 tablet and it meets the USP specs for weight,
20 thickness, content uniformity, assay, all those
21 things, that -- and there's -- and there's testing
22 to indicate that that batch meets those, validated
23 reliable testing, it's generally going to be safe
24 for the consumer; correct?

25 A. Right. Yes.

1 Q. Okay. Thank you.

2 (Exhibit 37, Recall Package 2009 was
3 marked for identification.)

4 Q. Exhibit 37, have you ever seen this
5 before?

6 A. I haven't gone through this.

7 Q. Does that mean that --

8 A. Well, it might have been in here. I
9 may -- I may have glanced at it. I don't recall
10 having read it.

11 Q. All right. This is the FDA approved
12 Recall Package for Digitek in April/May 2008. Okay?

13 Have you seen a Recall Package before?

14 A. Recall Package before? Not in years,
15 since I didn't have a lot of them.

16 Q. Okay. At the third page, under "Reason
17 for the recall," does it say Digoxin tablets
18 exceeded tablet thickness specifications?

19 A. Yes.

20 Q. Now, have you ever seen a batch record
21 for any other batch of Digitek, besides 70924, in
22 which tablets exceeded thickness specifications?

23 A. Have I looked at the batch records?
24 No. I've seen some evidence in E-mails and the like
25 that they were overweight, the tablets were

1 overweight, double tablets were overweight.

2 Q. Okay. Well, have you ever seen any
3 evidence, in any other batch record or any other
4 E-mail, or anything else, to indicate that the
5 tablets released to the market exceeded their
6 thickness specifications?

7 A. Exceeded the thickness? Can I look at
8 my report for one second?

9 Q. Yes.

10 A. Could you rephrase your question?
11 You can ask --

12 MR. KAPLAN: Why don't you have the
13 reporter read it back.

14 (Requested portion is read.)

15 A. Thickness? I would have to say I can't
16 recall at the moment.

17 MR. KAPLAN: Is that a no?

18 THE WITNESS: That's I cannot recall.

19 MR. KAPLAN: Yes or no?

20 THE WITNESS: I cannot -- I cannot
21 recall is my answer, if I'm allowed to give that
22 answer.

23 MR. MORIARTY: Can I follow up?

24 Q. I mean, this is a products liability
25 litigation over whether Digitek tablets exceeded

1 specifications and harmed consumers. Okay? It's
2 important for me to know whether you, as an expert
3 against my client in this case, have evidence,
4 documents, testimony, and the like, to indicate the
5 tablets that exceeded, and that's what I'm asking
6 you about right now, tablets exceeded thickness
7 specifications got to consumers.

8 A. Thickness -- can I look at an APR for
9 one second?

10 Q. A what?

11 A. An APR.

12 MR. MILLER: Certainly.

13 MR. MORIARTY: What's an APR?

14 A. I'm looking at a number of
15 out-of-specifications for blend uniformity.

16 Let me see.

17 Q. Remember my question involves tablets
18 that reached consumers.

19 A. Okay. For thickness, no.

20 Q. All right. Have you seen -- now, I
21 asked you this before lunch, I asked if you had seen
22 any evidence, or had an opinion to a probability
23 that out-of-spec tablets of normal size, but varying
24 API, reached consumers, and you told me no.

25 Do you have evidence now, after the

1 lunch break, that tablets of normal size with
2 varying API reached consumers?

3 A. Potentially.

4 Q. You potentially have evidence?

5 A. Yeah. Because you're talking about
6 probabilities, or possibilities.

7 Would you like me to go through it?

8 Q. No. You're talking about a blend
9 uniformity issue?

10 A. Correct.

11 Q. Did that batch --

12 A. The batches.

13 Q. -- test appropriately in finished
14 product testing?

15 A. They tested appropriately at end
16 product testing.

17 They found it -- can I clarify?

18 Q. I'm asking one question at a time.

19 A. Surely. Go ahead. Sorry.

20 Q. So they tested appropriately in
21 finished product testing; correct?

22 A. The end product testing sample that was
23 taken was within specification.

24 Q. Okay.

25 A. And at the very end of the process.

1 Q. All right. And at the blend uniformity
2 stage, and we'll get into the details of this
3 investigation way later, you're talking about one
4 out of the ten samples on the initial run was out of
5 spec; correct?

6 A. I don't know. The information I
7 received doesn't have that type of specificity.
8 I'm looking at the APR.

9 Q. You haven't reviewed the details of the
10 blend uniformity investigations that were done on
11 these batches?

12 A. No.

13 Q. Exhibit 37 contains -- has other
14 information in it like the health hazard evaluation.
15 Is that right?

16 And then a list of all the batches that
17 might be subject to the recall.

18 Is that correct?

19 A. Are we talking about the document I
20 have?

21 Q. Exhibit 37.

22 A. Okay. And your question is?

23 Q. Does it contain a health hazard
24 evaluation and a list of all the batches that might
25 be potentially related to the recall?

1 A. Normally it would have it, a health
2 hazard evaluation, and it should list the batches.
3 I'd have to go through it to confirm that, but...

4 Q. And do you know whether or not the
5 contents of a Recall Package are run past the FDA?

6 A. I'm not sure, but I -- it probably is.
7 Certainly I know of instances where it
8 is.

9 Q. I asked you earlier about Exhibit 39,
10 the July 2009 FDA statement about generic drugs, and
11 specifically the paragraph about Digitek.

12 Do you remember those questions?

13 A. I'd like to reread it, but I remember
14 we went over it.

15 Q. It's 38, Exhibit 38.

16 That information -- that information,
17 to your knowledge, is still on the FDA's website,
18 isn't it?

19 A. I have no reason to believe they took
20 it off.

21 Q. All right. And that would be available
22 not only to consumers, but to medical professionals?

23 A. The -- the information is available to
24 anyone who has an internet connection.

25 Q. And that would include consumers and

1 medical professionals.

2 A. They're part of that, yes.

3 Q. And that would include regulatory and
4 quality professionals in the pharmaceutical
5 industry. Is that correct?

6 MR. MILLER: Object to the form. It's
7 outside the scope. He's not here as an expert on
8 who's going to have access to the internet.

9 A. Common sense would tell you everybody
10 has access, and they are part of everybody.

11 Q. You -- do you have any reason to
12 believe that the FDA is -- has posted anything that
13 it believes is inaccurate in Exhibit 38?

14 MR. MILLER: Object to form.

15 A. Please ask that again.

16 Q. Sure. Would you assume that FDA
17 investigated the facts behind that posting and the
18 content of the posting?

19 MR. MILLER: Object to form.

20 A. Honestly, I don't know. I don't know.

21 I know they would check guidance
22 documents, etcetera. I don't know if they check
23 things like that, so I don't know who would do it.

24 Q. Did you review or rely on any materials
25 that are not listed in Appendix B to your report?

1 A. Did I rely on them? No.

2 Q. Did you bring anything with you today
3 in your binders, or other materials, that is not
4 listed in exhibit -- I'm sorry -- Appendix B to your
5 report?

6 A. Yes.

7 Q. What did you bring with you --

8 A. I brought everything that I made a copy
9 of.

10 Q. Do you know --

11 A. Which is everything that's pertinent
12 to -- to provide me information to try to make some
13 decision or some judgment.

14 Q. And you believe that there are some
15 things in those materials that aren't listed in
16 Appendix B?

17 A. Oh, I know there are. I know there
18 are, sir.

19 Q. All right.

20 A. That's why I brought them.

21 MR. MORIARTY: At some point, Pete,
22 we're going to have to go through the binders,
23 identify what's not in B.

24 MR. MILLER: Okay.

25 MR. MORIARTY: And I would prefer that

1 the court reporter take them, copy them, so that we
2 can have them, and then return what we remove from
3 Mr. Kenny's binders to Mr. Kenny, either directly or
4 through you.

5 MR. MILLER: Procedurally I have no
6 problem with that. Actually, I'd like to be part of
7 it and take a look at each document before it goes
8 to --

9 THE WITNESS: And will I be able to get
10 these documents back?

11 MR. MORIARTY: You will.

12 THE WITNESS: Within a reasonable
13 period of time?

14 MR. MORIARTY: You will.

15 A. Okay. You become attached to
16 documents.

17 Q. The report that you signed on June 15,
18 2010, that's your final report; correct?

19 A. That's the report I submitted, correct.

20 Q. And were there drafts of this report
21 before this final version?

22 A. Yes, there were.

23 Q. Did you bring drafts with you?

24 A. No. But I can.

25 The drafts are electronic.

1 I did not have an opportunity to go
2 through my files, because they're in multiple
3 places, to give you each iteration of what I did.

4 But I would go along and occasionally
5 save a copy at a certain period of time, and then
6 continue.

7 But I can provide that to you.

8 Q. Okay. Let's get back to where we left
9 off before the lunch break.

10 I was asking you a series of questions
11 about, you know, what would happen if a manufacturer
12 consistently put too much API in its batches, and
13 would it be detected.

14 And just before lunch you said, yeah,
15 likely it would, if the company or FDA was using
16 valid test methods.

17 Do you remember that?

18 A. Yes.

19 Q. And in the course of a long day like
20 this, when we're talking about a lot of different
21 documents and topics, sometimes we jump around and
22 sometimes, accidentally, I repeat myself. Okay?

23 A. Um-hum.

24 Q. So please excuse me if I do.

25 But have you seen any FDA citations or

1 warnings or observations indicating that Actavis did
2 not have validated test methods for Digitek?

3 MR. MILLER: Objection. Asked and
4 answered.

5 It's okay to answer.

6 A. I would have to look at the records.

7 And the reason I say that is an
8 out-of-specification result that has not been
9 investigated, you don't know if it's an assay issue,
10 or you don't know if it's a content issue. So
11 without the investigation, I can't tell you whether
12 the root cause of that, which goes back to when the
13 FDA found, as I did, out-of-specification tests, and
14 there is an adequate investigation, you don't know
15 whether it's a valid test method, a valid process,
16 you know nothing.

17 And then they retest and it looks good,
18 so they pass it.

19 Q. Did you see instances of out-of-spec
20 results in the materials that were not investigated
21 at all?

22 A. I saw instances where a root cause
23 determination could not be made, and I saw instances
24 where retesting was conducted, and on Digitek, and
25 without a root cause investigation, retesting of the

1 product and releasing it is not an acceptable,
2 compliant procedure, not an acceptable practice.

3 You cannot test the quality into a
4 product merely by taking a secondary sample.

5 Q. Do you always find a root cause when
6 you do an investigation?

7 A. Do you always find a root cause? No.

8 Q. What is the scientific judgment rule in
9 batch release?

10 A. Scientific judgment rule? It's not
11 scientific. It's do the numbers meet the
12 specifications. Science is not involved. The
13 people who review it are not scientists. They look,
14 is it filled in, are there results in specification,
15 are there any unexplained cross-outs, and the like,
16 but it is a rather routine review, and it's only is
17 by exception that it gets escalated to somebody with
18 a greater level of technical abilities.

19 Q. Again, we'll get to blend uniformity
20 failures in more detail later, but did FDA ever make
21 a 483 observation, or a warning letter observation,
22 to the effect that the lack of root cause
23 determinations in blend uniformity investigations
24 should have led to batch rejection?

25 A. I don't recall, the way you've phrased

1 it. I honestly don't recall.

2 I'd have to go back to the 483s. There
3 are 172 observations, or whatever it is.

4 Q. Did you see any information in any of
5 this material that the FDA asked Actavis to ever
6 recall Digitek batches before April of 2008?

7 A. I don't recall seeing anything.

8 Q. Is there an FDA reg anywhere which
9 specifically indicates that an out-of-spec test
10 result, 1 out of 10, at the blend uniformity stage,
11 mandates batch rejection?

12 A. There are -- I don't know if it's 1 out
13 of 10. What they specifically state is, if the test
14 results are out of specification, then you have to
15 follow a logical train of -- of investigation and
16 testing that's consistent with GMP.

17 So I can't tell you whether it is 1 out
18 of 10, or 2 out of 10, or 1 out of a thousand.

19 Q. All right. But what the reg
20 essentially says is, if you -- if you get an
21 out-of-spec result, you do an investigation;
22 correct?

23 A. Correct.

24 Q. It doesn't mandate batch rejection just
25 because you get an out-of-specification result, does

1 it?

2 A. That, in and of itself, would not
3 necessarily -- well, no. The batch would be
4 rejected -- the batch would be placed in quarantine
5 until an adequate investigation could be conducted.

6 After the investigation takes place,
7 there may be a determination that it's acceptable.
8 Perhaps they have done an investigation that's
9 acceptable to resample and retest, and then the --
10 in this case -- well, whatever. Did I answer your
11 question?

12 Q. Yes.

13 Whether it's at the blend uniformity
14 stage or at finished product testing, would I be
15 correct in saying that there are several different
16 reasons why there could be an out-of-spec?

17 A. Oh, my gosh. Of course.

18 Q. Okay. And some of them include
19 sampling errors. Is that right?

20 A. Yes.

21 Q. Math errors.

22 A. Sure.

23 Q. An out-of-spec test result in the
24 course of this does not necessarily mean a product
25 is, in fact, out of spec; correct?

1 A. It has to be assumed that unless you
2 have a root cause, that you cannot discount the fact
3 that a sample tested out of spec. You cannot take a
4 secondary sample, test it, and release a batch.

5 Q. Where is that in the regulations?

6 A. I can tell you that it is absolutely
7 100 percent industry practice, in every company.

8 If I ever saw a company, and I audited,
9 that went in, found no root cause determination, had
10 initial out-of-specification, decided that they were
11 going to resample, and that it was fine, I would --
12 I would have to take issue.

13 MR. KAPLAN: I move to strike the last
14 answer as non-responsive to the question.

15 Q. So if the root cause was determined to
16 be a math error, and on retest, it was fine, you
17 could release the batch; correct?

18 A. If you found a root cause, and if you
19 could discount, you could ignore, you could justify
20 the fact and understand the fact that samples were
21 out of specification, and it makes sense to you,
22 then you can, if you will, retest the product using
23 a sample inspection.

24 But it is very important that you have
25 to get the root cause determined.

1 I've never -- I don't think I've ever
2 released a batch, I'm sure I've never, where I had
3 initial out-of-specification, I couldn't figure out
4 why, and decided, for whatever reason, to retest --
5 it's okay to retest, but I would do it as a
6 diagnostic test, not as an acceptance determination
7 test.

8 At that point, it would become an
9 experimental batch, as far as I was concerned.

10 Q. Is blend uniformity sampling considered
11 difficult?

12 A. No. It should not be difficult.

13 Q. Do most companies struggle with blend
14 uniformity?

15 A. The companies I've worked with, content
16 uniformity is not, in general, a major issue.

17 Q. I was asking about blend uniformity.

18 A. Blend uniformity. I'm sorry.

19 No. It's -- I don't find, in the
20 companies that I work with, that blend uniformity is
21 an issue.

22 Q. Okay.

23 We touched a little bit before the lunch
24 break about batch yields.

25 Let's get back to that.

1 A. Surely.

2 Q. There's always going to be some waste,
3 for various reasons, in the pharmaceutical
4 manufacturing process of solid oral dose; correct?

5 A. Yes.

6 Q. And if, for whatever reason, a company
7 was consistently making double-thick tablets, the
8 batch theoretic -- or the yield numbers would not
9 match the theoretical numbers; correct?

10 A. I don't understand what "constantly"
11 means, but if --

12 Q. I said consistently.

13 A. Consistently. If they consistently --
14 I can't answer the question. I mean, I would say
15 that I have to know more about how many units you're
16 talking about, how often. I'd have to take a look
17 at the yield specifications. We'd have to do a
18 mathematical determination. Then, after that, we
19 could, you know, come to -- between the two of us,
20 come to a conclusion that, yes, it could be
21 affected, or no, it's -- it's buried within the
22 tolerances.

23 Q. Have you done such an analysis for your
24 work here?

25 A. As part of my work here, no.

1 I would need all the -- I would need an
2 unlimited amount of data.

3 This is something that Digitek is
4 expected to do -- or I'm sorry, Actavis.

5 Q. Have you ever seen anything in the FDA
6 documents, in your review of this case, to indicate
7 that there were double-thick tablets for any product
8 other than Digitek?

9 A. No.

10 MR. KAPLAN: Is there an answer?

11 MR. MORIARTY: He said no.

12 THE WITNESS: I didn't say that loudly?

13 MR. MILLER: It came across to me.

14 THE WITNESS: I'll try to be louder.

15 Q. Did you ever see any observations in
16 the 483s or the warning letters in which the FDA
17 asked Actavis to increase its sampling rate for
18 Digitek?

19 A. I don't recall seeing that, no.

20 Q. Have you ever actually seen a Digitek
21 tablet?

22 A. I've seen a picture of it on the
23 internet.

24 Q. So you haven't --

25 A. I haven't touched one.

1 Q. Okay. You haven't weighed one --

2 A. No.

3 Q. -- or anything like that?

4 A. No.

5 Q. You know what a Stokes BB2 tablet press
6 is?

7 A. Relatively, sure.

8 Q. Does Johnson & Johnson ever use them?

9 A. I don't believe they use them anymore,
10 but they certainly did years ago.

11 Q. Do you know when Johnson & Johnson
12 stopped using Stokes BB2 --

13 A. Well, you're talking about, again, a
14 \$60 billion company that has 140 operating units.

15 If you're talking about the experience
16 that I've had -- actually, I -- the companies I've
17 been with, we did not use Stokes.

18 Q. Is there any regulation, any FDA
19 regulation that specifies a particular age of
20 equipment, or type of equipment, that has to be used
21 for the manufacture of a solid oral dose product?

22 A. Age, no. Condition, yes.

23 Q. Okay. Condition.

24 Do you know whether or not the Stokes BB2
25 presses were in use for Digitek at the time of the

1 ANDA?

2 A. At the time of the information that
3 I've read, a Stokes press was being used.

4 Q. Is the fact that Actavis uses Stokes
5 BB2 tablet presses in all the batch records?

6 A. Is it -- I don't know. I'd have to
7 look through all the batch records.

8 Q. Did FDA ever make a 483 observation, or
9 a warning letter observation, to the effect that
10 Actavis should not be using Stokes BB2 tablet
11 presses to manufacture Digitek?

12 A. I don't recall that that -- that
13 suggestion was made.

14 Q. Are you an expert in manu -- tablet
15 manufacturing equipment with weight controls?

16 A. No, I'm not.

17 Q. Are you aware, from your review in this
18 litigation, that when UDL had Digitek tablets, it
19 performed random weight and thickness tests to make
20 sure that the tablets would fit into their blister
21 packs?

22 A. I saw testing being conducted. I don't
23 know how often, but I saw test results.

24 Q. Do you know whether UDL ever found
25 Digitek tablets that were outside the USP thickness

1 or weight specifications?

2 A. I would have no way of knowing that.

3 I would have -- I would have to see all
4 the results.

5 If I saw the results, then I could
6 say -- in random, then I'd say yeah, they're all in
7 spec.

8 Q. Well, when the Plaintiffs' lawyers
9 deposed the UDL employees, and had the UDL
10 documents, was there anything that came out in those
11 depositions, or those exhibits, to indicate that UDL
12 ever found tablets outside the USP weight or
13 thickness specifications?

14 A. I don't recall any instances.

15 Q. We touched on adverse event reporting a
16 little bit this morning.

17 How much do you know about the FDA's
18 adverse event reporting database?

19 A. Not a lot.

20 Q. All right. Are you aware that the FDA
21 generally considers that that system does not
22 reflect causation?

23 MR. MILLER: Object to form.

24 A. I'm not familiar enough and I couldn't
25 hazard a guess.

1 Q. All right. Okay. Would you prefer to
2 rely on pharmacovigilance experts to discuss issues
3 like that in this litigation?

4 A. Would I rely upon them?

5 I don't know who the experts are. You
6 know, I can't say I would or wouldn't.

7 I mean, people who say they're experts
8 are not necessarily experts.

9 Q. That's true.

10 You're not professing expertise in
11 pharmacovigilance, are you?

12 A. I have never professed that.

13 Q. Have you ever seen any data which
14 compares adverse event experience for Digitek with
15 that of any of its competitors?

16 A. Could you repeat that?

17 Q. Sure.

18 A. The statement "competitors."

19 Q. Have you ever seen any data that
20 compares adverse events experience for Digitek with
21 adverse event experience for any other Digoxin
22 product?

23 A. I don't recall. It would not be
24 something that I would have focused on because it's
25 outside of my expertise. I don't know what I would

1 do with the information.

2 Q. Have you read the depositions of any
3 doctors --

4 A. No.

5 Q. -- who have been taken in this case?

6 A. No. I have no interest.

7 Q. Do you know from any independent
8 research whether any hospital reported an increased
9 incidence of Digoxin toxicity in the years 2005,
10 '06, '07 or '08?

11 A. I did no investigation of any sort, so
12 the answer is I know of nothing, because I didn't do
13 anything.

14 Does that make sense?

15 Q. All right. Let me get back to some
16 statistics that I was asking you about before.

17 Of this 688.2 million tablets that were
18 part of the recall, do you have any opinion, to a
19 reasonable probability, as to what percentage of
20 them were outside the USP specifications on the low
21 side?

22 A. On the low side?

23 I have no way of knowing that.

24 Q. Do you have any opinion, to a
25 probability, of what percentage of those tablets

1 were out of spec -- out of the USP specifications on
2 the high side?

3 A. The -- the -- I'm sorry. Just repeat
4 the question so I can answer it correctly.

5 Q. Sure.

6 Do you have an opinion, to a reasonable
7 degree of probability, as to how many of the
8 recalled Digitek tablets were outside the USP
9 specifications on the high side of their active
10 pharmaceutical --

11 A. I would have no way of knowing that.

12 Q. Are you an expert in pharmaceutical
13 distribution?

14 A. No. No.

15 Q. And when I say distribution, just so
16 we're clear, I mean you work for J&J, which actually
17 makes pharmaceuticals and devices; correct?

18 A. I did work for them, yes.

19 Q. And then at some point, they might sell
20 or transfer the product to distributors who get it
21 ultimately on consumer shelves; correct?

22 A. Yes. I have some knowledge of it. I'm
23 not an expert on it.

24 Q. All right. That's what I want to find
25 out, is whether you have any expertise on the

1 distribution end of this, as opposed to quality and
2 manufacturing.

3 A. No. I've -- I've audited distribution
4 centers, but I haven't done it -- I look for GMP
5 issues.

6 Q. Just to make sure I'm clear, you would
7 have no opinion, to a probability, as to any
8 specific Digitek batch, as to how many of those
9 tablets were outside their USP specifications;
10 correct?

11 A. Well, you say "any." There is a lot of
12 information on Batch 70924, so I -- I would have an
13 opinion on whether or not additional tablets were --
14 of double thickness or were thick that went out. So
15 I would have an opinion on that.

16 Q. Okay. Other than that.

17 A. Other than that --

18 Q. If I went through the list of 152
19 batches that actually made it to market, that had to
20 come back, you would have no opinion to a
21 probability as to any of them other than 70924?

22 A. No. No. I would have to say, no,
23 that's not correct.

24 When I evaluate a company, I evaluate
25 it for all those control systems and procedures that

1 can affect the quality of the outgoing product.

2 When I see a company that has most of
3 their systems out of control, if you will, or not
4 within control, or examples where they're not within
5 control, I have a high level of concern that the
6 product they are releasing is not conforming to
7 specification. I know it -- I know it's adulterated
8 because of all the GMP issues. The question is,
9 does it meet specification.

10 I would have a very high level of
11 concern with that. I would have -- and I don't
12 know, does that help answer my question -- or your
13 question?

14 Q. Are you done with your answer?

15 A. I think so.

16 Q. Okay. Well, I don't mean to repeat
17 myself, but I need to make sure I understand this.

18 Based on your review, you have a high
19 concern about this, whether product met
20 specifications; correct?

21 A. I have a very high concern about it.

22 Q. Okay. But if -- but if I understand
23 it, you've never seen reports of double-thick
24 tablets in the hands of consumers, or pharmacists,
25 from recall batches. You've never seen lab tests

1 of --

2 A. Of what?

3 Q. -- of out-of-spec tablets; correct?

4 A. Lab tests of out-of-spec tablets in the
5 field?

6 Q. Yes.

7 A. Okay. Well, there are plenty of tests
8 that are unreleased batches.

9 Q. But --

10 A. It's --

11 Q. -- unreleased batches aren't in the
12 hands of consumers, are they?

13 A. That's not -- that's correct.

14 Q. Okay.

15 A. But they are a high level of concern
16 because they implicate the quality of those that
17 have been released.

18 Q. Well, isn't the purpose of the Quality
19 Department to reject batches that are out of spec
20 for some reason?

21 A. The primary objective of the Quality
22 Assurance Department is to make sure that controls
23 and systems are in place. That's the primary
24 responsibility.

25 A secondary responsibility, as a safety

1 net, is to take samples at the end of the process
2 and test them.

3 But the primary -- it's a very, very
4 small part of what Quality Assurance and Quality
5 Control does.

6 Q. If a company finds a batch that's out
7 of spec, truly out of spec, it should be rejected;
8 correct?

9 A. If they find a batch that's truly --
10 well, of course.

11 Q. So Batch 8022 --

12 A. The "truly" part is --

13 Q. Well, 80228, which, from your review,
14 had tablets that were out of spec by weight was
15 rejected; correct?

16 A. Was rejected? No. Not all of them
17 were rejected.

18 Q. Do you think 80228 went to market?

19 A. I'd have to -- I'd have to look at the
20 record. May I?

21 Q. Sure.

22 A. I don't know if they went out to
23 market. In the records I looked at, I don't know if
24 they were released.

25 I'd love to have seen 2008 APRs because

1 then it could confirm to me whether or not they were
2 released.

3 MR. KAPLAN: I'm going move to strike
4 the last answer. It's not responsive.

5 THE WITNESS: It's what?

6 MR. KAPLAN: Not responsive to the
7 question that was asked. It is a gratuitous
8 statement.

9 Q. All right. Let me just -- I -- I
10 believe I've asked this, and I don't mean to ask it
11 over and over again.

12 I thought I heard you say on several
13 occasions today that you have no evidence in the
14 material you have reviewed of out-of-spec Digitek
15 tablets actually in the hands of consumers.

16 MR. MILLER: Objection.

17 Q. Am I correct about that?

18 MR. MILLER: Objection. Misstates the
19 previous testimony.

20 Q. Then I guess I have to keep asking.

21 A. Could you ask it again?

22 Q. Because if it did --

23 A. Could you ask it one more time?

24 Q. Mr. Kenny --

25 A. Could you rephrase it?

1 Q. I'll get there. Okay? I want to make
2 it clear to you.

3 I understand that you have GMP concerns
4 about my client and you have concerns about whether
5 Digitek was within or without the specifications;
6 correct?

7 A. Correct.

8 Q. And I've shown you all kinds of 484s
9 where the FDA tested the product; correct?

10 A. That's correct.

11 Q. And documents with Celsis labs tested
12 the product and it all met the specs; correct?

13 A. Of what the -- evidence I've seen,
14 correct.

15 Q. Done by sampling plans chosen by Celsis
16 and the FDA pursuant to the U.S.; correct?

17 A. Well, it was a sampling plan of just
18 taking a few units. It was done by a sampling plan.

19 Q. Done by the U.S. -- according to USP
20 methods; correct?

21 A. Yes.

22 Q. And FDA regards the USP as essentially
23 the bible, so far as the chemical testing of
24 product; correct?

25 A. You can use the term "bible." They

1 certainly consider it a knowledgeable and valid
2 source of testing.

3 Q. All right. And you know that the 152
4 recalled Digitek batches all had quality control
5 testing on them for finished product; correct?

6 A. I will assume that they did.

7 Q. And will you assume that they used the
8 USP validated method that the FDA was aware of?

9 A. The method that they -- no. What I --
10 what I can assume -- I don't want to assume
11 anything, but for the sake of this -- this
12 conversation, or this discussion, the methodology
13 that they have in their test method is probably the
14 USP method.

15 Now, did they adequately train the
16 person to perform that analysis? Did they
17 adequately do verification batches to basically
18 validate that the method is acceptable, when tested
19 in their hands, I have seen no evidence to suggest
20 that they've done that.

21 Q. Well, you've seen no evidence from FDA
22 that indicates they didn't; correct?

23 A. For -- for what?

24 Q. The Digitek testing.

25 A. If you -- okay. You're talking about a

1 population here of all products.

2 Q. No. I'm talking about Digitek.

3 A. I understand that.

4 MR. MILLER: But let the man answer.

5 You are, but I object to the form. You're
6 interrupting him.

7 A. It -- it's sort of like a Venn diagram.
8 Here's the population. If you say that they're
9 using practices that are out of compliance, the
10 assumption will be since Digitek -- Digitek is part
11 of that large diagram, that they also suffer in many
12 of the issues that are suffered across the plant.

13 Q. I asked you hours ago whether you ever
14 saw a specific finding from the FDA that Digitek was
15 adulterated, and you said no.

16 MR. KAPLAN: Object to form.

17 MR. MILLER: Object to form. Misstates
18 previous testimony.

19 MR. MORIARTY: I don't think it does,
20 but...

21 Q. Find for me in the documents a specific
22 statement by the FDA that Digitek was adulterated.
23 Find one, please.

24 A. Why would -- why would a company --

25 Q. Find one, please.

1 We've already gone over the recall
2 notice.

3 MR. MILLER: Objection.

4 Q. We've gone over the Recall Package.
5 You can't ask me why the company would do that
6 because I get to ask the questions. That's my
7 prerogative today.

8 What I want you to do is show me
9 somewhere in the material you reviewed FDA finding
10 that this product, Digitek, that this litigation is
11 about, was adulterated.

12 MR. MILLER: Objection. Asked and
13 answered.

14 THE WITNESS: I beg your pardon?

15 MR. MILLER: That's okay. Answer it.

16 A. I don't recall where Digitek -- Digitek
17 was, let's say, clearly stated.

18 Q. Okay.

19 A. Does that answer your question?

20 Q. Yes.

21 Now, if you had a client in your
22 consulting business and you wanted to know whether
23 GMP issues with -- overall were impacting on a
24 specific product, would you look at batch records
25 for that specific product?

1 A. That would be a portion of my
2 investigation.

3 Q. And do you think FDA would do that?

4 A. I would assume. I -- I would expect
5 them to take a look at batch records.

6 If the batch records are not
7 necessarily accurate representations of what
8 happened.

9 Q. You have no evidence in this case that
10 Actavis --

11 A. No.

12 Q. -- has Digitek batch records that are
13 inaccurate in any respect, do you?

14 A. That's correct.

15 Q. Now, let's talk about Batch 70924.

16 A. Okay.

17 Q. In your opinion, to a probability, were
18 there more double-thick tablets in 70924 than the 20
19 they found during the investigation?

20 A. I believe. With a high level of
21 certainty, that, yes, there were.

22 Q. How many?

23 A. I have no clue. I just know there were
24 more.

25 Q. How do you have a high level of

1 certainty about that?

2 A. Because visual inspection is regarded
3 as, and it's in my experience, and as an industry
4 acceptance, that visual inspection is horrendously
5 unreliable to the point that it cannot be relied on.

6 Q. Is that any kind of visual inspection?

7 A. No. No. It could be -- I'm talking
8 about human inspection.

9 At best it's a safety net.

10 Q. So you have a high degree of certainty
11 there were more, but you don't know how many more;
12 correct?

13 A. Correct.

14 Q. Certainly couldn't have been 4 million
15 more; right?

16 A. I would think it would not be 4 million
17 more.

18 Q. And you've never seen a report from any
19 consumer that they got a double-thick tablet in
20 2008; correct?

21 A. Correct.

22 Q. 70924 wasn't shipped to market until
23 2008; right?

24 A. I don't know.

25 Q. Have you seen a report from any of the

1 litigants in this case, any of the Plaintiffs that
2 they had an actual double-thick tablet?

3 A. No. I don't know who the litigants
4 are, but I haven't seen that.

5 Q. Have you seen any report from a
6 pharmacist that there was a double-thick tablet
7 found in 2008?

8 A. 2008? No.

9 Q. Do you think that with all these
10 Plaintiffs' lawyers scouring the country for
11 double-thick tablets, they might have found one if
12 there was one?

13 MR. MILLER: Object to form.

14 A. I can't -- I can't speak to that. I
15 don't know what they did.

16 Q. In the material that you reviewed to
17 prepare opinions was Reference 54 in Appendix B.

18 It's an article called, "Stop Depending
19 on Inspection."

20 Do you remember that?

21 A. Yes, sir.

22 Q. Is the journal from which this comes --
23 it's called "Quality Process."

24 Do you subscribe to that journal?

25 A. I currently do not. I have for years.

1 Q. Does Quality Process --

2 A. Progress.

3 Q. -- Progress, I'm sorry, apply to a
4 number of different manufacturing fields?

5 A. Yes, it does.

6 Q. Not just pharmaceuticals?

7 A. Yes, it does.

8 Q. Is this a peer-reviewed publication?

9 A. Is it peer-reviewed? I don't know.

10 Q. Do you know the author of this article?

11 A. No, I do not know the author.

12 Q. Well, here at page 40 in this article,
13 it says, "Because 100 percent inspection is only
14 80 percent accurate, even companies that do
15 100 percent inspection will allow one out of five
16 defects to slip through."

17 Do you see that in your -- this
18 article?

19 A. Yes. That's basically from Juran.

20 Q. What's Juran? J-U-R-A-N?

21 A. J-U-R-A-N. He invented -- basically
22 formulated the current, or at least were the
23 pioneers of the current quality practices, and in
24 Juran's book, he comes up with the 80/20, basically
25 stating that a 100 percent inspection is not

1 100 percent effective.

2 Q. Was there a --

3 A. And he claims -- he claims that there
4 have been studies done that have corroborated that
5 over and over.

6 As a matter of fact, he gives an
7 example where every time, or frequently, he would go
8 to a conference, or whatever, and he'd ask a certain
9 question, and they would respond to -- it looks like
10 you may have it.

11 And, apparently, he sees a high -- high
12 number of people who get that wrong, and -- but it
13 is one of the most consistent, generally-accepted
14 numbers that I'm aware of.

15 Q. Were the studies Juran relied on -- or
16 relied on published?

17 A. Were they published? I'm sure they
18 were, because he -- he references -- I don't know,
19 is really the correct answer.

20 He reference -- references a study, but
21 I don't know if the reference is correct. But he is
22 a rather reputable gentleman, or was.

23 Q. Well, is it going to be your opinion
24 that the 100 percent inspection of Batch 70924 was
25 allowed 20 percent of the tablets through as

1 defective?

2 A. I -- I would not claim that.

3 Q. Okay.

4 A. What I would say is that it would not
5 be 100 percent effective.

6 The issue is that the methodology was
7 not validated, it was not qualified. There was no
8 way of them knowing what level of detection is
9 possible based upon the operators, the methodology,
10 the through-put, without an understanding of how
11 reliable the inspection method is --

12 Q. Is that -- go ahead.

13 A. Without an understanding of the
14 inspection method, you basically are dealing in an
15 unknown area.

16 So you -- you would make the assumption
17 that it is an invalid inspection.

18 It could have more than 20 percent. It
19 could have less. There's no way of knowing.

20 Q. And even assuming there were
21 double-thick tablets in 70924, that somehow evaded
22 the 100 percent inspection, do you think they also
23 evaded the tightened AQL inspection that followed?

24 A. The tightened AQL inspection is not --
25 it's not much of a -- a challenge.

1 It tested 1250 tablets out of
2 4.7 million.

3 The probability that they would detect
4 levels of -- of 1, 2 is very low.

5 Q. And --

6 A. In fact -- go ahead.

7 Q. Go ahead.

8 A. I said, in fact, the sampling method
9 they used would allow -- would accept on one reject,
10 which is an incredible, I would say, violation of
11 the whole quality assurance practice.

12 Q. You'd certainly agree that
13 Batch 70924 A got more inspections than any other
14 batch that you're aware of.

15 A. I think it did. I'd say more
16 inspections.

17 Q. Yes.

18 A. It got -- it got 100 percent
19 inspections, purportedly.

20 Q. So even if there were some unknown
21 number of double-thick tablets that made it into
22 containers and went to Mylan, and then downstream to
23 consumers, you don't know how many of them were in
24 any given drugstore; correct?

25 A. Correct.

1 Q. In any given container that a consumer
2 received; correct?

3 A. Correct.

4 Q. Whether they went to California, or
5 Oregon, or Florida, or anywhere else; correct?

6 A. I have no idea where they went.

7 Q. Wasn't the tightened AQL developed
8 under the highest level of scrutiny under the mill
9 standard 105 that you referred to earlier.

10 A. The -- it was --

11 Q. First of all, yes or no?

12 A. Well, the way you phrased it, no.

13 Q. Okay. What do you disagree with about
14 that question?

15 A. Could you repeat the question?

16 Q. Was the heightened AQL inspection that
17 was done on Digitek Batch 70924 done under mill
18 standard 105?

19 A. That's not what you asked.

20 Q. Okay. I'm asking you a new question.

21 A. Oh, the new question. I got it.

22 MR. MILLER: He asked you to repeat the
23 question. He was assuming that's what you were
24 doing. So now it's a new question.

25 Q. I'm sorry. Go on.

1 A. So you're asking what -- sorry. Now
2 you have to repeat it.

3 Q. Was the 70924 heightened AQL inspection
4 done according to mill standard 105?

5 A. I believe it was, yes. I looked at the
6 numbers and it looks correct.

7 Q. Was that the highest level of scrutiny
8 under mill standard 105?

9 A. I don't recall, but I don't believe so.
10 I'd have to go through 105, but I don't
11 believe that's the -- highest standard meaning the
12 highest level of scrutiny, no. I don't think so,
13 but I'm not sure.

14 Q. Certainly 100 percent is a higher level
15 of scrutiny than a heightened AQL of that nature;
16 correct?

17 A. Not necessarily, no.

18 Q. Now, I asked you a little bit ago
19 whether you had an opinion to a probability as to
20 numbers of tablets that were below or in excess of
21 the USP's API specs.

22 Do you remember those questions?

23 A. Sure.

24 Q. And you said you had no opinion as to a
25 probability as to whether those numbers were high or

1 low; correct?

2 A. Could you repeat it again? I want to
3 make sure that I'm answering the question.

4 MR. MORIARTY: Read my question back,
5 please.

6 (Requested portion is read back.)

7 MR. MILLER: I object to the form.

8 A. I'm not --

9 MR. MILLER: I'm not so sure I
10 understand what you're asking.

11 Q. Let me get to my numbers.

12 All right. Out of 152 recalled
13 batches, if you do the math, it's roughly 688 of
14 a million tablets. Okay?

15 A. I recall, yes.

16 Q. I asked you whether you had an opinion
17 to a probability as to what percentage of those were
18 outside the USP specs high, and you said you had no
19 such opinion to a probability.

20 Am I correct on that?

21 A. Of the number. You asked me if I have
22 a probability of a certain number.

23 I have no idea what the number could
24 have been.

25 Q. Okay. And I asked the same question as

1 to low, and you had the same opinion; correct?

2 A. Yeah. I have no way of knowing how
3 many were low.

4 Q. Now, even assuming, if there were some
5 that were outside the specs high --

6 A. Um-hum.

7 Q. -- you would have no opinion to a
8 reasonable probability as to how high.

9 Is that right?

10 A. Well, I know --

11 MR. MILLER: Objection.

12 A. I know there's some double thickness,
13 but -- I'm not sure I can answer the question
14 without hearing it again. I'm sorry. I must be
15 getting tired.

16 Maybe this is an a good time for a break.

17 Q. Let's finish this, and then we can take
18 a break.

19 Even if there were some number of
20 Digitek tablets among the recalled batches that were
21 outside the USP specs high --

22 A. Right.

23 Q. -- do you have an opinion, to a
24 reasonable degree of probability, as to how far
25 outside the specs high they were?

1 MR. MILLER: Object to form.

2 You can answer.

3 A. I have no way of knowing.

4 Q. All right. Same thing on the low side.

5 A. I have no way of knowing.

6 Q. Okay.

7 MR. MORIARTY: All right. If you want
8 to take a break, let's take one now.

9 THE VIDEOGRAPHER: Stand by. We are
10 going off the record. The time is 2:52 P.M. This
11 is the end of Tape No. 4.

12 (Recess was taken.)

13 THE VIDEOGRAPHER: We are back on the
14 record. The time is 3:02 P.M. This is the
15 beginning of Tape No. 5.

16 Q. Have you ever -- Mr. Kenny, have you
17 ever seen any evidence in the material that you
18 reviewed that Digitek was ever cross-contaminated
19 with another product made at Actavis during this
20 time?

21 A. I saw that cleaning validation wasn't
22 adequate, but I didn't see a product that was
23 cross-contaminated.

24 Q. Technically speaking, it was not the
25 cleaning validation that was inadequate, it was

1 cleaning validation studies that they found
2 inadequate; correct?

3 A. Well, that's -- cleaning validation
4 is -- cleaning validation, you automatically add the
5 studies on the end.

6 Q. Well, what the FDA was concerned with
7 was not the cleaning itself, but how you tested
8 whether the cleaning was adequate; correct?

9 A. Yes. But that's cleaning validation.

10 Q. I just want to be technically correct.

11 A. And recovery.

12 Q. Okay. But you never saw any evidence
13 in anything that there was cross-contamination at
14 any point, did you?

15 A. I saw no evidence.

16 (Exhibit 21, Amide Investigation Final
17 Report, was marked for identification.)

18 Q. Now, in the materials you reviewed, and
19 commented on in your report, was Plaintiff's Exhibit
20 128, which my team also marked as Defendant's
21 Exhibit 21.

22 That's the double-thick tablet
23 investigation from 2004; correct?

24 A. Correct.

25 Q. And are you aware that the tablet at

1 issue was actually made in a batch in 2003?

2 A. Yes.

3 Q. And there was only one. Is that
4 correct?

5 A. Only one what?

6 Q. Tablet.

7 A. There's only -- I believe that's
8 correct.

9 Q. And it was found by a pharmacist.
10 Is that right?

11 A. I believe that's correct.

12 Q. Now, I asked you before about the math
13 of this, but if the recall Digitek from mid-2006
14 forward was 688 million tablets, if we did the math
15 from 2003 forward, the number of Digitek tablets
16 made and distributed would be in the billions;
17 correct?

18 A. If you say so.

19 I have no way of knowing those numbers,
20 but there's probably a lot of them.

21 (Exhibit 20, Summary of Findings, was
22 marked for identification.)

23 Q. I want to hand you what's been marked
24 as Exhibit 20.

25 Have you seen this document before?

1 A. This was just submitted to me. I have
2 not had a chance to review it.

3 Q. This is a 2004 EIR, is it not?

4 A. It appears to be. It says "EI," which
5 tends to mean inspection report.

6 Q. There are three things I want to ask
7 you about in this document.

8 So first I'd like you to go to
9 page 4.

10 Let me ask you a preliminary question.

11 In order to be under consent decree, do
12 you have to be in compliance with GMPs?

13 A. In order -- you have to repeat that.

14 Q. In order to stay under consent decree,
15 do you have to be in compliance with GMPs?

16 A. Yes.

17 Q. Now, go to page 4, the first paragraph
18 under "History Of Business Operations," the fourth
19 line down, it says -- it's referring to a consent
20 decree that was in effect from '92 to 2001.

21 It says, "The consent decree was lifted
22 in 2001 following successful demonstration of
23 sustained cGMP compliance."

24 Do you see that?

25 A. Yes.

1 Q. And these EIRs, these are FDA
2 documents.

3 Is that right?

4 A. Correct.

5 Q. Now I'd like you to go to page 6. In
6 the paragraph about field alert reporting, the --
7 first of all, are you aware that Actavis notified
8 the FDA of this 2004 double-thick tablet episode,
9 they notified the FDA through a field alert.

10 Is that right?

11 A. That is correct.

12 Q. And towards the bottom of the paragraph
13 I'm referring to, down here, it says, "No additional
14 complaints or reports of thick tablets have been
15 reviewed for this high-volume product."

16 Do you see that?

17 A. Yes, I see that.

18 Q. "The event was considered an isolated
19 incident, and corrective actions were put in place
20 to prevent its reoccurrence."

21 Do you see that?

22 A. Yes.

23 Q. Do you have any reason to disagree with
24 the FDA about the statement it made in its EIR at
25 that point in time?

1 A. Yes.

2 Q. And what's the basis for your
3 disagreement with the FDA?

4 A. Because their investigation, in my
5 opinion, based upon my experience, was not adequate.
6 It did not --

7 Q. In 2004?

8 A. In 2004.

9 In other words, there -- a complaint is
10 being handled.

11 At that particular point, a very
12 thorough investigation would have been expected,
13 which I did not see.

14 Q. Did FDA criticize, observe or warn --

15 A. I don't recall.

16 Q. -- Actavis about its investigation?

17 A. I don't recall.

18 Q. Well, don't you think they would have
19 said so in this EIR, had they been concerned about
20 it?

21 MR. MILLER: Objection to form.

22 A. I can't tell you what the FDA would
23 have said.

24 Q. Okay. Let's go to page 9.

25 Under "Complaints," the second

1 paragraph.

2 It says, "A larger number of complaints
3 was also noted for Digoxin tablets; however, it is
4 the highest volume product, 179 batches manufactured
5 in 2003/2004, according to the list of batches
6 produced per year. There were also no trends
7 observed for the types of complaints."

8 Do you have any reason to disagree with
9 the FDA about those comments?

10 A. I have no reason to disagree.

11 Q. Do you have any criticism of FDA's
12 investigation of the field alert that Actavis filed
13 with them in 2004 about this tablet incident?

14 A. I have no opinion on it.

15 Q. And are you -- you're aware, are you
16 not, that tablets made in 2003 would not have been
17 included in the recall in 2008?

18 A. Yeah. They would not have. I'm
19 assuming they would not have been within expiration,
20 so they would not have been included.

21 Q. Now, I told you earlier that I was
22 going to make sure that we had -- we knew all the
23 material you brought with you today, and things of
24 that nature.

25 Okay?

1 These are some documents from your
2 file.

3 I don't know if they were actually
4 pulled from binders.

5 First of all, did you have exchanges of
6 E-mail with the Plaintiffs' lawyers in this case?

7 A. There's been some correspondence, yes.

8 Q. Who's been your primary contact with
9 the Plaintiff's lawyers?

10 A. I would say Meghan, primarily.

11 Q. Have you had contact, other than today
12 and maybe yesterday, with Mr. Miller or his firm?

13 A. Oh, sure. He was always carbon-copied,
14 or most of the time.

15 Q. But there's been exchange of E-mail?

16 A. Yes.

17 Q. Have you printed all the E-mails?

18 A. I did print them. I don't have them
19 with me.

20 Q. All right.

21 A. What I tried to do, just for the
22 record, is I tried to take the E-mail that had the
23 long list, as opposed to -- that covered each of the
24 replies, as opposed to, you know, taking each one
25 individually.

1 Q. All right.

2 A. You may find it in there. I didn't
3 find it this morning when I went through it.

4 Q. So this particular document is
5 something about Juran's Quality Control Handbook.
6 Is that right? About the 80/20 rule?

7 A. Yeah. I tried to quote what was in
8 his -- his documentation -- his book, which I have.
9 I've had the book for 20-plus years.

10 Q. And here you have Plaintiff's Exhibit
11 133?

12 A. Yep.

13 Q. And it has handwriting on it?

14 A. Yes, it does.

15 Q. Is that your handwriting?

16 A. Yes, it is.

17 Q. And this has to do -- 133 has to do
18 with Quantic's -- Quantic Regulatory Services'
19 investigation, doesn't it?

20 A. It's hard to tell what it has to do
21 with because it's all blank.

22 Q. Well, let me make this easy for you.
23 In your own handwriting, in the middle
24 of the page, doesn't it say "Quantic" with the arrow
25 towards the people on the E-mail?

1 A. Yes. Actually Sal Romano wrote that.
2 He told me that that is Quantic. I would have no
3 way of knowing that because I didn't know who it
4 was.

5 Which is meaningless to me other than
6 the fact that they are a consulting firm.

7 Q. Now this document does not have a --

8 A. Right.

9 Q. -- exhibit sticker on it, and the Mylan
10 Bates number is kind of copied off of the document,
11 but it's a report of December 4, 2006 about an
12 audit.

13 A. Yes.

14 Q. Is that right?

15 A. Yeah. You're not really showing it to
16 me, but I believe it is.

17 Yeah. I know that document.

18 Q. This document that I'm holding looks to
19 be the consent decree from 1992; right?

20 A. Yes.

21 Q. This document I'm holding is not Bates
22 stamped, and it has no exhibit sticker.

23 Would you agree with that?

24 A. Yes.

25 Q. It is a November 6, 2006 letter to FDA

1 on Actavis letterhead, is it not?

2 A. Yes, it is.

3 One second. One second.

4 Q. You can hold it.

5 A. Okay. Right. Okay.

6 Q. When did -- is it Mr. Romano or

7 Dr. Romano?

8 A. Dr. Romano.

9 Q. When did Dr. Romano cease working on
10 this Digitek matter?

11 A. Probably around a month ago.

12 Q. The next document in the stack that I'm
13 holding looks like Exhibit 69 from the Galia
14 deposition.

15 Is that right?

16 A. Yes.

17 Q. This is a -- this is deposition Exhibit
18 159.

19 Is that right?

20 A. Yes.

21 Q. "Blend failure investigation"?

22 A. Right.

23 Q. Now, it has Russ's name above the top
24 redactions. And Sal's name.

25 What's that all about?

1 A. Let me look at it.

2 Q. First of all, there's handwriting all
3 over it. Is that right?

4 A. Right. Yes.

5 Q. Okay. Why are Russ and Sal's
6 names above that --

7 A. Because I -- I don't want to touch this
8 because I know nothing about technical sampling. I
9 looked at it, and I tried to read it, and I tried to
10 understand. It was foreign to me. I didn't
11 understand the -- some of the terminology. I
12 attempted to, and I said, this is something for
13 either Russ, or if Sal knows something about it,
14 perhaps he can add some insight, which -- which he
15 did not.

16 Q. All right. Well, this has to do with
17 blend failure investigation, and there are at least
18 two Digitek batches named in this investigation.

19 Is that right?

20 A. I'd have to see it, but I'm sure you're
21 right.

22 Correct. Yes.

23 Q. So if I understand this correctly, you
24 at least looked at this document.

25 A. Correct.

1 Q. Is that right?

2 But then because you did not consider
3 yourself to be expert in what they're talking
4 about --

5 A. The sampling technique, correct.

6 Q. -- you had Russ and Sal look at it;
7 correct?

8 A. No. I put a note that Russ and Sal
9 should look at this.

10 Q. And do you know if they did?

11 A. I -- I -- since I never communicated
12 with Russ, I assume if he did, it was by his own
13 volition.

14 Sal, I believe, did take a look at it,
15 and he couldn't add my more depth than I could.

16 I had difficulty following it.

17 Q. Is that because this blend uniformity
18 sampling and investigation material that's discussed
19 in here is really quality control chemistry issues?

20 A. I don't know what the issues are. I
21 can tell you that I don't understand the methodology
22 that's used in order to obtain a representative
23 sample. They were using terms I'm not familiar
24 with.

25 Q. Are you -- have you ever been a quality

1 control chemist?

2 A. No. I explained that earlier.

3 Q. Okay. The next document I'm holding is
4 an article called "Drugs with narrow therapeutic
5 index as indicators in the risk management of
6 hospitalized patients."

7 A. Yes.

8 Q. Did you read this article?

9 A. I tried to read it.

10 Q. This is --

11 A. Then I realized it was -- quite
12 honestly, I had no familiarity with the term, so I
13 went onto the internet to at least see what the term
14 meant, and then I realized when I went into it -- I
15 tried reading it, just to familiarize myself, but it
16 was clearly out of my territory.

17 Q. All right. And attached to it is
18 deposition Exhibit 164, 165, and 166.

19 Is that right?

20 A. Yes.

21 Q. Okay. The last document I'm holding
22 here appears to be a draft, "for discussion purposes
23 only," version of your report.

24 Is that right?

25 A. Correct.

1 Q. To whom did you send this draft?

2 A. I sent it to Meghan, Sal and Pete.

3 Q. Was this a first draft?

4 A. That was a first draft. The first
5 draft that they saw, right.

6 Q. And then in here, there's handwriting.
7 Is it your handwriting?

8 A. All of it's mine.

9 Q. Is the handwriting based on discussions
10 you had with Plaintiffs' counsel about the draft?

11 A. It is based upon two things, or three,
12 if you will.

13 One, listening to them.

14 Secondly, coming up with ideas as I'm
15 just going through the document.

16 And then later, going back and looking
17 at and making additional edits as I reread it.

18 Q. Are you left-handed?

19 A. Yes, I am.

20 Q. Did you go to Catholic school?

21 A. High school.

22 Q. Backwards checkmarks, telltale sign.
23 Takes one to know one.

24 MR. MORIARTY: Do you want me to mark
25 these as one exhibit? How do you want to take this

1 up, because at some point, I need to have more time
2 to go through them, and see if I have questions
3 about them.

4 MR. MILLER: I'd like to mark them as
5 individual exhibits, but something like the article
6 with the three exhibits attached to it can stay as
7 one exhibit. I mean, we don't need to break it up.
8 But things that are together should stay together,
9 and those that are apart should stay apart.

10 MR. MORIARTY: What I'd like to do is
11 give these all to the court reporter --

12 MS. CARTER: Are you talking about
13 those specific handfults? Aren't we going to make
14 copies of the whole thing?

15 MR. MORIARTY: Well, we'll get there in
16 a minute. These is what I'm talking about right
17 now. I'll give them to the court reporter.

18 I will confer with the people in my
19 office as to where we are in exhibits, and then give
20 her the numbers so she can mark them.

21 MR. ANDERTON: We are at the 91.
22 We've -- and we've already used 100.

23 MR. MORIARTY: Well, that's where we
24 were yesterday. Is that okay?

25 MR. MILLER: Okay.

1 MR. MORIARTY: We still have to go
2 through these to see if there are things that were
3 not in Appendix B, but I don't need to mark
4 everything he brought.

5 MR. MILLER: I'm fine with reading the
6 title of what he brought that's not in Appendix B
7 into the record, if that works for you.

8 MS. CARTER: I didn't know if you
9 wanted to or not.

10 Q. Are you going to be able to readily
11 identify what is in these binders that is not in
12 Exhibit B?

13 A. No. I'm -- not readily. Sorry.

14 Q. So you don't have the E-mails with you
15 today.

16 Do you have all the attachments to the
17 E-mails here today?

18 A. Attachments to E-mails.

19 I don't know if there were any
20 attachments to E-mails.

21 Like the instructions of -- you know,
22 legal instructions in deposition.

23 I don't -- I can't, off the top of my
24 head, recall any electronics exchanged other than
25 late copy of the -- on June 15, I think it was, of

1 the draft, or thereabouts.

2 Q. All right. Well, at some point I need
3 you to print -- I need you to get us the E-mails. I
4 need you to print the drafts.

5 MR. ANDERTON: No. I want them
6 electronically.

7 THE WITNESS: Okay.

8 MR. MORIARTY: He wants them
9 electronically.

10 THE WITNESS: So how should I do that?

11 MR. MORIARTY: Put them on a thumb
12 drive.

13 THE WITNESS: No, I mean how to copy
14 it.

15 MR. ANDERTON: Just transfer them onto
16 some sort of portable drive, thumb drive, disk.

17 A. I'm not trying to be overly technical.
18 But how do you take an E-mail and copy it? You
19 don't even know where the file is located.

20 MR. MILLER: I'd have to go with him on
21 that. If told me to put an E-mail on a thumb drive,
22 I'd have no clue how to do it.

23 MR. MORIARTY: If you -- if you keep --
24 if you keep an -- if you keep an electronic Digitek
25 file and you keep the E-mails in the file, they

1 should be there.

2 MR. MILLER: I think the notice asked
3 for a hard copy. I think -- I think it satisfies
4 your request if he prints them out and provides you
5 with a hard copy. He's not going to provide you
6 with an electronic copy.

7 MR. ANDERTON: The note does not ask
8 for just a hard copy -- or the notice does not ask
9 for just a hard copy.

10 I will accept hard copies of the
11 E-mails, subject to your preserving and not
12 destroying any of the electronic copies.

13 THE WITNESS: Certainly.

14 MR. ANDERTON: And with respect to
15 non-E-mails, other drafts I believe you testified
16 about earlier, that you maintain you still have in
17 electronic format --

18 THE WITNESS: Yes.

19 MR. ANDERTON: -- I want those
20 electronically.

21 Anything except an E-mail that relates
22 to this case that you maintain electronically and it
23 isn't part of the binders here, other drafts in
24 particular, you're going to need to transfer onto
25 some sort of portable media.

1 THE WITNESS: That's easy.

2 MR. ANDERTON: Okay. Fair enough. And
3 can -- and there's to be no dealing -- no modifying
4 it electronically. Transfer it, hand them the
5 media --

6 MR. MILLER: They will be PDFs, they're
7 not going to be Microsoft Words.

8 MR. ANDERTON: No. I don't want PDFs.
9 I want them --

10 MR. MILLER: You're going to get PDFs.
11 Yeah, I mean, you know, if you're going to take a
12 software and dissect this thing until he gets to the
13 first letter he typed in, I know that kind of stuff
14 is out there. He's going to give you a PDF, and
15 that's what you're going to get.

16 MR. ANDERTON: That's not acceptable to
17 me.

18 MR. MILLER: We will --

19 MR. MORIARTY: Wait. I don't want to
20 take up my deposition time. Preserve everything
21 you've got in your computer on Digitek, and we'll
22 take this up later.

23 THE WITNESS: Okay.

24 MR. MORIARTY: We're not going to agree
25 on this on my record.

1 Q. Do you have any knowledge of which
2 consumers, or which Plaintiffs in the Digitek
3 litigation, received which batches of Digitek?

4 A. Which consumers received what batches.

5 MR. MILLER: Object to form.

6 A. I'm not sure I understand the question.
7 You mean from the distribution center?

8 Q. From anywhere. I mean, Batch 70924
9 went to market; correct?

10 A. Yes.

11 Q. And presumably it was disseminated to
12 pharmacies, and some of it, potentially, to
13 consumers.

14 Is that correct?

15 A. Yeah.

16 Q. Right?

17 A. Yes. Yes. I'm sorry.

18 Q. First of all, do you even know for a
19 fact whether any consumers got tablets from 70924
20 before the recall?

21 A. I have no way of knowing that.

22 Q. Okay. So if I went to other batches in
23 the recall and mentioned them by number, would you
24 have any way to know which consumers got tablets
25 from those batches?

1 A. No. I don't have any way of knowing.

2 Q. Do you know anything about how the
3 die -- die table set for Stokes BB2 tablet presses
4 is adjusted?

5 A. No. That's not my expertise.

6 Q. Do you have any idea what percent of
7 pharmaceutical manufacturers have tablet presses
8 with weight controls?

9 A. I have no way of knowing that.

10 Q. Have you reviewed any manufacturing
11 documents from Actavis Elizabeth?

12 A. I don't believe so. No, I don't think
13 so. I don't recall any.

14 Q. How many of the 483s between 2006 and
15 2008, January 2006 to April of 2008, specifically
16 refer to Digitek?

17 A. Specifically refer to Digitek. I would
18 say there's -- I'd have to look through them, if
19 you'd allow me. But I think there's --

20 Q. How many?

21 A. -- specifically, one. That's -- I
22 don't -- I'd have to look at them, honestly.

23 If you want me to go to the 483s, I can
24 go through them.

25 Q. Well --

1 A. When you say "specifically," you mean
2 that mention Digitek?

3 Q. Yes.

4 A. There's several.

5 Where Digitek's name is part of the --
6 is included in the 483.

7 Q. All right. Well, to save you time,
8 here's what I see, and you tell me if you remember
9 any other instances, and if you want to look at the
10 documents, fine.

11 In December of -- or February of 2006,
12 the FDA had a 483 about adverse report -- adverse
13 incident reporting.

14 A. Correct.

15 Q. You remember that one?

16 A. Yes.

17 Q. Then in August of 2006, there was this
18 cleaning validation test method; correct?

19 A. Correct.

20 Q. And the AER reporting was fully
21 remediated; correct?

22 MR. MILLER: Object to form.

23 A. I don't know if it was or wasn't.

24 Q. That's not your area of expertise?

25 A. No. No, it's not.

1 Q. Was the cleaning validation test method
2 observation remediated?

3 A. I believe it would have been, yes. But
4 I -- I don't recall specifically. I didn't
5 reconcile it.

6 Q. Okay. And then from my review, there
7 are three straight 483s, October of '06, November of
8 '06 and September of '07 in which Digitek is not
9 mentioned at all.

10 Do you remember that?

11 A. I'd have to look at them. I suspect
12 that if you looked through it and you don't see
13 Digitek named, that is accurate. If you want me to
14 take a look at it, I will.

15 Q. In May of 2008, there were two comments
16 about Digitek. One had to do with blend uniformity
17 investigations and the other had to do with 70924.

18 Do you remember that?

19 A. I remember those instances, yeah.

20 Q. All right. If you need to look at the
21 483s, I want to make sure that those are the three
22 483s which contain any reference to Digitek
23 specifically.

24 Do you need to check?

25 MR. MILLER: Object to form.

1 MR. MORIARTY: What's the matter with
2 the form?

3 MR. MILLER: It's misleading. Your
4 whole line of questioning was -- was about
5 mentioning Digitek specifically, and then you
6 changed to summarizing it with -- with mentioning
7 Digitek in any way. I forget how you mentioned it.
8 We can certainly take a look at it again.

9 Q. Why don't you check the 483s and tell
10 me if there are any other 483s, besides the three I
11 mentioned, that refer to Digitek.

12 MR. MILLER: Period.

13 A. That use the term "Digitek" in there.

14 Q. Yes. As a product.

15 A. Okay. I understand that. But if there
16 is -- so I can get clarify here. If they say that
17 all so-and-so systems are -- are included, do you
18 want me to tell you that I believe that Digitek is
19 part of that universe?

20 In other words --

21 Q. No. I'm asking you about Digitek
22 specifically referred to.

23 A. I'm trying to answer you for Digitek.

24 But if you say something about "all" or
25 "every," it means that Digitek is part of the "all"

1 or "every," or would be singled out as an exception.

2 So if I went through it, I'd have to
3 say, okay, here are the ones that say Digitek and
4 here are the ones that are -- that are -- are across
5 all operations, and, therefore, Digitek is part of
6 that, even though the name isn't there.

7 I'd have to literally go through -- we
8 could go through line by line. It would be easy.

9 Q. I'm asking you about a product, not a
10 system.

11 A. A product. Okay. So now ask the
12 question again. Maybe I can help you better.

13 Q. Do you need to look at the 483s to tell
14 me whether or not Digitek is specifically mentioned
15 in any more than the three that I've told you about?

16 A. I do not need to go through it to try
17 to find -- do a word search for the name Digitek. I
18 will take your word that that's correct.

19 Q. All right. Now, you've seen references
20 in some of these documents to a total failure of the
21 quality system, haven't you?

22 A. Yes. Yes.

23 Q. When FDA has tested Digitek, at least
24 seven times just in the recall batch period alone,
25 and the product met USP specifications every time,

1 you can't have a total failure of a quality system
2 regarding Digitek and repeatedly pass USP --

3 A. That's absolutely not true.

4 It depends on what you mean by total
5 failure.

6 Total failure, to me, means that you've
7 incurred a huge risk in terms of releasing product,
8 whether it be Digitek, whether it be the other drug
9 products, and by -- by having this huge risk, it's
10 a -- it's a huge problem.

11 Q. Well, you said in your answer it
12 depends what you mean by total failure.

13 A. Yeah.

14 Q. What do you mean by that?

15 A. What do I mean by what?

16 What do I mean by total failure?

17 Q. No.

18 A. Total failure --

19 Q. No. You said, it depends what you mean
20 by total failure.

21 What do you mean by that? Does that
22 mean that total failure is in the eyes of the
23 beholder?

24 A. Of course it is.

25 Q. Are you talking about total failure of

1 the quality system from a regulatory standpoint?

2 A. Versus what?

3 Q. My question stands by itself.

4 A. From a regulatory standpoint, is it a
5 total failure? If I was using the word "total
6 failure," I would say from a regulatory and a
7 quality control standpoint, it is a failure.
8 "Total" is not a good word to use.

9 Because it -- it's difficult to
10 quantify.

11 Q. But certainly --

12 A. It's a significant failure.

13 Q. Certainly product quality, as defined
14 by the specifications, can still be met under these
15 circumstances; right?

16 A. Is it conceivable? Yes.

17 Q. Well, isn't it a fact when FDA tested
18 seven of the recalled batches itself?

19 A. It is -- if you're asking the question,
20 can you, in a total failure mode, produce some
21 product that is acceptable, yes, it can. Whatever
22 "total failure mode" means.

23 Q. And if some -- and if -- even if we
24 accept the FDA's statement that there was a --
25 somebody's statement that there's a total failure of

1 the quality system, that does not tell you if there
2 was out-of-spec Digitek in the hands of consumers,
3 or if there was, how much there was; right?

4 A. That -- just that term, no. It has
5 no -- no precision to it whatsoever.

6 Q. Was there ever a statement by -- I'm
7 sorry. Let me rephrase that.

8 Was there ever a final agency
9 determination, in any FDA document, that there was a
10 total failure of Actavis's quality systems?

11 A. I don't know if they used that term.
12 I think what -- the only term that I
13 recall definitely is when people tried to paraphrase
14 what they felt the FDA either could call the outcome
15 or -- that type of reference.

16 Q. Do you ever go on FDA's website and
17 study their statistics about compliance actions?

18 A. Oh, sure.

19 Q. Do you know how many warning letters
20 were issued in 2008 by the FDA?

21 A. No. No, I don't recall.

22 Q. Do you recall how many recalls there
23 were?

24 A. No.

25 Q. Would it surprise you if there were

1 2,721?

2 A. Recalls?

3 Q. In 2008?

4 A. Would it surprise me? It may surprise
5 me. It's a little bit higher than I would have
6 thought.

7 Q. Do you know how many 483s were issued?

8 A. No. It's got to be tens of thousands.
9 It's got to be many.

10 Q. Do you -- do you know how often FDA
11 issues a 483, percentage-wise --

12 A. It's in --

13 Q. -- when they do an inspection?

14 A. All I know is I didn't get any.

15 Q. I would assume that other parts of J&J
16 got plenty of 483s; right?

17 A. They -- other companies did get 483s,
18 surely, just not mine.

19 Q. Now, before I shift gears and get to
20 your resume and your actual report, let me ask you
21 an open-ended question.

22 If I asked you to prove to me that
23 tablets outside the specifications for active
24 pharmaceutical ingredient actually reached
25 consumers, how would you go about doing that?

1 A. I'd take a look at all of the -- first
2 of all, all of the exceptions, all the
3 out-of-specifications, all the deviations, all of
4 the departures, whatever -- the exceptions that were
5 done; in other words, the non-conformances that
6 occurred, I'd take a look at those first. And then
7 determine whether or not, based upon that, there's a
8 reasonable probability that material would be
9 released to the market. That would be the very
10 first step, which was a big step; meaning
11 energy-wise.

12 Q. Okay. Then what would you do?

13 A. Then --

14 Q. To check -- because at this point,
15 you're working with the hypothesis, the
16 reasonable -- I'm sorry. Let me withdraw that.

17 I would assume you'd also look at batch
18 records and quality control testing.

19 A. That would not be my first step. The
20 others I'd --

21 Q. I'm not asking if it's your first step.
22 I'm asking whether it's --

23 A. You said approach.

24 Q. -- a step.

25 A. Is it a step? Sure.

1 Q. I mean, you'd want to know whether the
2 product passed blend uniformity, in-process testing
3 and finished-product testing, wouldn't you?

4 A. Yes.

5 Q. Okay. What would then be the next
6 step --

7 MR. MILLER: Objection to form.

8 A. You got me out of order. The second
9 step would be looking at complaints.

10 Q. Okay.

11 A. And I would look at, did consumers
12 receive product that either they had some type of
13 medical issue, or some type of alleged issue with
14 the conformance of the product to what their
15 expectations were.

16 Q. Okay.

17 A. And then I'd go through those records,
18 and I'd determine how many were confirmed and how
19 many were not confirmed. With the confirmed, I'd
20 say the customer got a product that was out of
21 specification, because they sent a sample and it's
22 out of spec.

23 Q. Okay.

24 A. Then I would -- this is off the cuff,
25 but what I eventually -- if your question is would I

1 what eventually look at the batch records,
2 absolutely. I would take a sampling of the batch
3 records. I wouldn't look at them all unless, for
4 some reason, I wanted to totally quantify it.

5 Q. Okay. Anything else?

6 A. Let me think about the systems.

7 I would look at -- yeah. I would look
8 at systems that affected the quality of the product.
9 I'd take a look at process validation.

10 Basically I would do an audit. I would
11 look at raw material acceptance. I would look at,
12 as you said, batch records. I'd look at preventive
13 maintenance. I'd look at calibration. I'd look at
14 in the labs, at lab notebooks, to try to scrutinize.

15 I'd look at standard solutions. I'd
16 see how they controlled those, and whether or not
17 it's consistent with GMP.

18 I'd go into the micro lab. I'd look
19 for -- sometimes they have a certain water quality.
20 Normally companies do an annual report of water
21 quality. And then I'd take a look at the water
22 quality test results themselves.

23 I'd go into the micro lab. I'd take a
24 look at the facility itself. I'd take a look at the
25 equipment. Was it qualified? I'd ask questions

1 regarding the validation -- or the qualification,
2 rather, of those instruments, for example, an
3 incubator. I'd ask whether or not it would have
4 been properly qualified, the temperature
5 distribution, whether they used qualified methods or
6 qualified equipment to do that.

7 I'd go through the analytical lab. I
8 would determine whether or not the equipment that's
9 used to test has been properly qualified.

10 I'd look at the training records of
11 those people that did the tests, to see that they
12 were properly trained.

13 I would then follow through with -- on
14 a manufacturing level -- all -- all the areas I felt
15 that were -- could impact on the quality of the
16 product.

17 Basically as thorough a job -- again,
18 if I wanted to find out as a -- as comprehensively
19 as human -- humanly possible, I would do that type
20 of thing.

21 And I have done stuff comparable to
22 that.

23 Q. You did not do all of that in this
24 instance; right?

25 A. I did not, sir.

1 Q. All right. Now -- but if you're
2 reviewing the internal documents, like the exception
3 reports, the out-of-specs, the deviations, the batch
4 records and the system reviews, what you wind up
5 with there essentially is a hypothesis of, maybe we
6 did or maybe we did not send defective product out
7 into the marketplace; correct?

8 A. You'd have to repeat that question.
9 If you do -- if you do an analysis from
10 what standpoint?

11 Q. The analysis that you just gave; right?

12 A. Right.

13 Q. You --

14 A. I talked about the exceptions. That
15 would have been the first thing.

16 Q. I understand that. But at the end of
17 that, if you're just looking at the internal
18 material, at the end of that --

19 A. Internal material.

20 Q. The company's material.

21 A. "Material" meaning chemicals, product?

22 Q. Everything you just described except
23 the --

24 A. Those are records, documentation,
25 etcetera.

1 Q. -- complaints. Okay. Everything you
2 described, but the complaints.

3 A. Yeah.

4 Q. You just come up with a hypothesis that
5 out-of-spec tablets went out; correct?

6 A. No. I would have enough information,
7 perhaps, to begin to find instances where product
8 got out the door.

9 I mean, I would look at stability. If
10 stability failed, product out the door was out of
11 specification.

12 Q. All right. I understand that. But did
13 you see any -- in the material you reviewed, were
14 there stability failures for Digitek?

15 A. For Digitek, I don't recall seeing
16 them.

17 Q. What I'm trying to find out is your
18 scientific method to -- in your instance, you've
19 been consulted, how do you prove that defective
20 tablet actually got out? Okay? It seems to me that
21 at the end of what you just described, except for
22 the product complaints, so far you cannot actually
23 prove that defective product left the premises?

24 A. No. The -- what I would say is -- now,
25 as part of the investigation, I would look at

1 retained samples. I would test retained samples.
2 When there's -- there's enough for a duplicate assay
3 for every single batch we produce.

4 I would test raw material components.

5 I would -- a lot of raw material
6 components are received on certification.

7 I would probably do redundant testing
8 to make sure that, again, we didn't have -- we
9 didn't have unacceptable raw materials.

10 Q. What if it passed?

11 A. If it passed, then I would continue my
12 investigation until I exhausted all those things
13 that I felt could be contributory.

14 Q. What would constitute proof to you,
15 just from the internal documents, that
16 out-of-spec -- let me rephrase that question. Okay?

17 You've got -- let's assume you've got a
18 very low number of out-of-spec investigations.

19 A. Right.

20 Q. Okay? Let's assume that you have no
21 out-of-spec finished tablet testing.

22 A. Okay.

23 Q. Okay?

24 A. "Finished" meaning commercially-sold
25 product --

1 Q. Yes.

2 A. -- where you take your sample and --
3 and use it to release. We're not talking about
4 stability, we're not talking about any other
5 extra -- extraordinary testing.

6 Q. Well, let me -- let me continue.

7 A. Okay.

8 Q. You have a very low number of blend
9 uniformity issues. You have no out-of-spec finished
10 product testing. You have no stability failures.

11 A. The terms you're using -- I should let
12 you complete your sentence.

13 Q. Because stability testing is done after
14 release; correct?

15 A. Right. It's frightening. We find out
16 months, if not years, later that what you sold is no
17 good.

18 Q. Okay. But you're doing this review
19 after the fact because you're being consulted.

20 A. You mean --

21 Q. After a company has released the
22 product, they call you in because they want to know.
23 Okay?

24 So if you've got these things,
25 essentially, going for the product, at what point do

1 you say, I think there's proof that there was
2 defective product that's in the marketplace?

3 A. As soon as I find a few instances where
4 there's -- where there was defective product.

5 Q. Okay.

6 A. And then I say, you know, do you want
7 me to continue to go and try to quantify, try to
8 figure out what batches, you know, it depends on the
9 level of scrutiny that you want.

10 The FDA, for example, when they go in,
11 when they see two or things wrong with a certain
12 system, they may not continue looking at that,
13 because they found out that the system is not
14 adequate.

15 Q. All right. And if you were --

16 A. And that's their approach.

17 Q. If you were called in on a consulting
18 job like this, for the part about the customer
19 complaints, would you have hired one of your
20 colleagues to come in and do the pharmacovigilance
21 analysis of the customer complaints?

22 A. Wait. Pharmaco, I would, myself, want
23 to go through, which I consider arguably the most
24 important feed-back from the customer, which are
25 customer complaints. I would go through. I would

1 ask for a summary of all the complaints. I would
2 ask for some explanation of what they consider
3 critical, what they would consider trivial.

4 I would then ask them to sort, because
5 they'd be in an electronic base, I'd ask them to
6 sort what -- you know, the -- what we both perceived
7 as being potentially critical.

8 I would then look at the levels, the
9 incident levels, of those critical issues. If you
10 have multiple batches that had the same issue,
11 multiple products, it's 16 complaints within one
12 batch and almost none in others. So I'd look at the
13 trends, and then I would, myself, go through those
14 batches that were critical, and those complaint
15 records that are alleged to be critical, I would go
16 through those and review those myself, because I
17 would consider it that important.

18 Q. Okay. Did you personally consult
19 directly with a pharmacovigilance expert in your
20 work on the Digitek cases?

21 A. Not at all.

22 Q. Have you seen any reports of an expert,
23 or from the FDA, that says that there was a
24 pre-recall signal in the AER data to indicate that
25 there was a problem with the drug?

1 A. I'm not sure what that term is.

2 I guess not, because I'm not familiar
3 with that term.

4 Q. Which term?

5 A. Pre --

6 Q. Pre-recall?

7 A. Pre-recall -- what is that?

8 Q. Signal?

9 A. Signal. I don't recall that term.

10 Q. To put it another way, has any
11 pharmacovigilance expert told that there was data
12 pre-recall to indicate that there was a problem with
13 Digitek in the field?

14 A. Well, the only thing I recall was that
15 this was -- this was one of the top, I believe
16 number 3, most complained about product, if you
17 will, with the most issues. So they needed a
18 high -- they wanted a high level of scrutiny. That
19 might have been a document from my line.

20 Q. Well, didn't the FDA, in that EIR that
21 I read you from a little bit ago, say that it was
22 the highest volume product, or one of the highest
23 volume products?

24 Yes?

25 A. Yes. Yes.

1 Q. And didn't the FDA say that it was no
2 trend to the adverse event reports?

3 A. I believe that's what they said.

4 Q. What I'm trying to find out --

5 MS. CARTER: Objection to form.

6 Q. What I'm trying to find out from you is
7 whether you have consulted with or seen the report
8 of FDA, or an expert, to indicate that there was
9 some pre-recall signal, some pre-recall evidence
10 that there was --

11 A. Associated with adverse experience.

12 Q. -- problems -- problem with the Digitek
13 in the field from customers.

14 A. From customers? I don't recall seeing
15 that.

16 MR. MORIARTY: How far are we on the
17 tape?

18 THE VIDEOGRAPHER: We have about
19 another 28 minutes left.

20 MR. MORIARTY: All right. Let's -- we
21 need to take a five-minute break because my
22 colleague needs to leave. Okay?

23 THE WITNESS: Sure. I could use it.

24 THE VIDEOGRAPHER: Stand by. We are
25 going off the record. The time is 3:54 P.M. This

1 is the end of Tape No. 5.

2 (Recess was taken.)

3 THE VIDEOGRAPHER: We are back on the
4 record. The time is 4:09 P.M. This is the
5 beginning of Tape No. 6.

6 Q. When were you first contacted about
7 being an expert in this case?

8 A. Oh, I'm going to guess in February,
9 perhaps.

10 Q. Of what year?

11 A. Of this -- I'd have to -- I think it
12 was February of this year.

13 Q. And who contacted you?

14 A. Actually, Sal Romano contacted me.

15 Q. Who contacted Sal?

16 A. John Kowalski contacted Sal.

17 Q. Who is John Kowalski?

18 A. John Kowalski is a gentlemen, he and I
19 worked -- someone I worked with, a microbiologist,
20 who does consulting. He took a retirement package
21 similar to what --

22 Q. Who contacted Mr. Kowalski?

23 A. I don't know. Somebody from the law
24 firm.

25 Q. I assume you're charging Plaintiffs for

1 the time you spend reviewing records, writing
2 reports, and things of that nature.

3 A. For the most part.

4 Q. What are you charging them?

5 A. I'm charging \$430 an hour.

6 Q. And then today, I assume I'm being
7 charged for the time spent questioning you; right?

8 A. Yes. I want to be sarcastic, but I
9 won't be.

10 Q. How much are you charging me?

11 A. Whatever the rate would be.

12 Q. \$430 an hour?

13 A. Yes.

14 Q. How did you come up with \$430 an hour?

15 A. We were told that they would pay 400.

16 We -- they asked us to bring in an expert on
17 tableting. As part of standard consulting
18 agreements, he would have been part of the SpyGlass.
19 We decided that that was not the best use of Russ,
20 but then we had a loss of income, so we said that we
21 would like to get for ourselves another \$30 an hour,
22 which we said did seem fair enough. So each of us
23 went from 400 to \$430 an hour.

24 Q. When you say "each of us," are you
25 talking about you and Sal?

1 A. Sal and -- Sal, so when Sal billed --
2 bills -- billed, he would get \$430 an hour, also.

3 Q. And how was it -- I'm sorry. Were you
4 done?

5 A. Yes.

6 Q. How was it decided that you would sign
7 the report and testify, as opposed to Sal?

8 A. Because Sal's schedule would not
9 allow -- the visits, the deposition dates, the
10 potential trials, he's beyond busy.

11 Q. All right.

12 A. So it sounded like something he could
13 do to begin with, and he felt he couldn't do it.

14 Q. And then did -- the Plaintiffs sent you
15 some material; correct?

16 A. The Plaintiffs sent me material --

17 Q. Plaintiff.

18 A. Yes.

19 Q. And you reviewed it?

20 A. Correct.

21 Q. Did you have a full opportunity to read
22 whatever they sent you?

23 A. Yeah.

24 Q. Did you have an opportunity to ask them
25 for additional documents if you wanted to?

1 A. Yes.

2 Q. Did you -- did they let you know that
3 there were depositions going on of various company
4 witnesses?

5 A. No.

6 Q. You never knew that?

7 A. I suppose I knew it.

8 I didn't -- it wasn't important to me.

9 Q. All right. Did you --

10 A. Because it's the facts and data that I
11 wanted to look at. I didn't -- quite honestly,
12 never went through the deposition process, so it
13 wasn't totally clear to me what -- what all these
14 records -- what records would be collected,
15 etcetera, and what would be available.

16 Q. So after you reviewed what they sent,
17 did you ask to see any additional data?

18 A. I asked to see a ton of additional
19 data.

20 Q. Did you get the data you asked for?

21 A. I received what they had.

22 MR. KAPLAN: That's not the question.

23 Q. Did you ask for anything that you
24 didn't get?

25 A. I'm sure, yeah. I'd have to go back

1 through what I requested, but, yeah.

2 Like I requested to go to the -- an
3 audit, and it just -- just didn't seem -- later on,
4 it just didn't seem practical or worthwhile.

5 Q. Okay. Anything else that you asked for
6 that you didn't get?

7 A. I suppose there is. I'd have to go
8 backwards -- or I'd have to go back in time and
9 reconstruct that.

10 Q. Would that be documented in the
11 E-mails, or other materials --

12 A. That may be documented, yeah.

13 Q. And then after reviewing whatever you
14 did have available, you wrote a report.

15 Is that right?

16 A. That is correct.

17 Q. And your signature appears at page 35
18 of that report.

19 Is that right?

20 A. Correct.

21 Q. And you had all the opportunity to
22 write this and include what you thought were the
23 significant things about this litigation.

24 Is that right?

25 A. If it was available.

1 Q. And you had --

2 A. I was told that the information is what
3 it is at that point.

4 Q. And you had an opportunity later, after
5 writing a first draft, to discuss it with the
6 Plaintiffs' lawyers.

7 A. That's right.

8 Q. And it's come to this final version;
9 correct?

10 A. Correct.

11 Q. And you were aware that the purpose of
12 this was to put us on notice of all your opinions
13 about my client, Actavis, and Mr. Kaplan's client,
14 Mylan; right?

15 A. Yes.

16 Q. And you tried to do that?

17 A. I did it as well as I knew how.

18 Q. According to your resume, you got your
19 bachelor's degree in mechanical engineering.

20 Is that right?

21 A. That's correct.

22 Q. And then you did some graduate work at
23 Iowa State?

24 A. That's correct.

25 Q. Did you -- did you get a degree from

1 Iowa State?

2 A. I did not.

3 Q. You did some graduate work in
4 biomedical engineering at the University of Rhode
5 Island?

6 A. Correct.

7 Q. Did you get a degree from the
8 University of Rhode Island?

9 A. No, I did not.

10 Q. At that point, you went and started at
11 Ethicon; correct?

12 A. Ethicon, Inc.

13 Q. Was that all devices?

14 A. That was devices, correct.

15 I worked at quality assurance
16 supervisor, and where we did certain level of
17 inspection, visual inspection. That was
18 ineffective. And I worked as -- I will call it a
19 validation engineer for the last two-plus years.

20 Q. Do you have any of the Six Sigma
21 degrees or --

22 A. I have a lot of training, yeah.

23 Q. Well, do you -- do you get degrees
24 or --

25 A. Yeah, I have a -- I have a green belt.

1 Q. Okay. And is -- is the Six Sigma
2 System valuable in -- in what you do?

3 A. Is it valuable? It's a tool. And if
4 used properly, it can be valuable.

5 It sometimes is almost the opposite,
6 but...

7 Because there's an expectation of what
8 it can do that's not achievable.

9 Q. All right. Then you worked from '86 to
10 '89 -- wait a minute.

11 A. Then I went to Corporate.

12 Q. Well, what did you do between '79 and
13 '86?

14 A. '79 and '86, I worked in
15 Johnson & Johnson International, which became
16 Johnson & Johnson Corporate. I ended up going back
17 there again. You know this HIV company I explained
18 to you? Well, we went out of business, and as we
19 closed the doors, I was looking for a job. There
20 were people, apparently, even though I didn't know
21 them, at Corporate who said, we'd be glad to have
22 you, you know, temporarily. I had no interest in
23 going back to the job, meaning full-time. So I
24 worked there for almost two years until I found
25 something that I felt was -- would use my skills.

1 So I worked a total, I'll say, nine --
2 say nine-plus years at Johnson & Johnson Corporate.

3 Q. On any specific products?

4 A. All products. I -- I constantly moved.
5 I can give you a little history, but it's up to you.

6 Q. When you were with Ortho Pharmaceutical
7 from '86 to '89, was any of that solid oral dose?

8 A. Yeah. 90 percent.

9 Q. Did you work on any patch technology?

10 A. Patch -- no. It was not -- it was not
11 a viable technology at Ortho at that particular
12 time, that I recall.

13 I didn't work on it.

14 Q. '89 to '91, you were at IOLAB.

15 A. IOLAB, correct.

16 Q. That's another Johnson & Johnson
17 company?

18 A. Yes.

19 Q. Was it solid oral dose?

20 A. No. It was interocular devices,
21 implantable devices, and also phacoemulsifier,
22 emulsifiers, which are electronic instruments used
23 during surgery, and we did -- they did chemicals,
24 but I don't think they're -- I don't think
25 they're -- no. They're a device, not a drug.

1 Q. '92 to '95 at Advanced Care Products,
2 was that solid or oral dose?

3 A. No. That was topical.

4 Q. '95 to '97, Direct Access Diagnostics.
5 Was that solid oral dose?

6 A. No, it was not.

7 Q. Johnson & Johnson CPWW from '98 to '04.
8 Was that solid oral dose?

9 A. There was -- there was one, but there
10 were two to three, different -- most of it was
11 topical, and we did have some solid dosage form
12 products.

13 Q. When you worked on solid oral dose
14 products at Johnson & Johnson, did you ever have
15 batches that were put on hold?

16 A. Did we -- of course.

17 Q. Did you -- I assume you rejected
18 batches from time to time?

19 A. Rejected batches from time to time,
20 yes.

21 Q. I didn't ask you this when I was asking
22 you about what you charge for litigation consulting,
23 but do you know what you charged the Plaintiffs'
24 lawyers to date for this litigation?

25 A. Well, I have one bill in. I don't

1 remember exactly, but we just got paid. Probably --
2 I don't remember. 20-some-odd-thousand would be for
3 me.

4 Q. Billed?

5 A. Billed. Yeah. I would get about
6 \$25,000.

7 Q. And how much unbilled time do you have?

8 A. I don't know. But it's probably
9 equivalent to that.

10 Q. So you may have as much as \$40,000
11 worth of work into this case even before today?

12 A. Yeah, I would say yeah.

13 Q. 40 or 50.

14 A. Yeah, I put in a lot more hours that
15 I'm not billing, but when you put in a 16-hour day,
16 I bill for 8.

17 Q. Have you talked -- other than with
18 somebody from Motley Rice, or Pete Miller, and Sal,
19 have you talked to anybody else about this
20 litigation?

21 A. Not a human being, other than they know
22 I'm doing some kind of litigation. That's it.

23 Q. Do you advertise yourself as an expert
24 in any trade journals of any type?

25 A. No. No. I do not.

1 Q. Have you seen the expert reports of any
2 of the other Plaintiffs' experts in this case?

3 A. No. Not a single one.

4 Q. Do you have any military experience?

5 A. ROTC.

6 Q. Where?

7 A. University of Dayton. It was required
8 first two years.

9 Q. Where are you from originally?

10 A. New Jersey. Jersey City I was born in.

11 Q. Have you ever had a faculty position at
12 any school?

13 A. No.

14 Q. Have you ever published any articles
15 about quality work in the pharmaceutical industry?

16 A. I -- I have published, if you will,
17 within Johnson & Johnson Worldwide. I was the
18 creator of Johnson & Johnson Worldwide guidance
19 documents when I was there, and I wrote procedure --
20 not procedures guidance documents, that affected all
21 companies worldwide. So they would read it and they
22 would use that as a minimum acceptable approach
23 to -- to -- that quality control subject.

24 Q. Have you ever published anything
25 outside Johnson & Johnson?

1 A. No. I had no interest in doing it.

2 Q. Have you ever taught at any seminars on
3 quality assurance outside --

4 A. Seminars, no. I trained --

5 Q. -- outside J&J?

6 A. Outside J&J, no.

7 Q. So do you consider yourself to be an
8 expert in regulatory for the pharmaceutical
9 industry?

10 A. I consider myself an expert on systems
11 and controls.

12 Q. Quality systems?

13 A. Quality systems and controls.

14 MR. KAPLAN: Was that "no" to
15 regulatory?

16 THE WITNESS: Well, it encompasses
17 regulatory. It's interpretation of regulatory and
18 in real fashion.

19 My -- my objective -- my objective --
20 well, I can explain it. My objective --

21 MR. KAPLAN: Well, he's asking the
22 question. I just didn't hear. I didn't know
23 whether you -- he asked the question, do you
24 consider yourself an expert in regulatory affairs.

25 THE WITNESS: In regulatory affairs --

1 MR. KAPLAN: And I didn't hear that.

2 A. Regulatory affairs is a much bigger
3 picture. I do not consider myself expert on
4 regulatory affairs. Regulatory affairs would --
5 would go into reporting. It would go into other
6 aspects, medical aspects, which I have no -- no
7 experience in, and no interest.

8 Q. In Tab 3 of the documents that were
9 contained in your Appendix B is a 483 from 2004.

10 Do you remember that?

11 A. Well, I've read them all, so, yes, I
12 would remember it.

13 Q. This precedes the recall of Digitek;
14 right?

15 A. 2004, yes.

16 Q. And --

17 A. Do you want me to pull the document?
18 Is that worthwhile?

19 Q. Digitek isn't mentioned in this 483, is
20 it?

21 A. I don't know. I'd have to look at it.

22 Q. I'm handing you my copy of that 483.

23 A. The name "Digitek" does not appear on
24 that document.

25 Q. And since this precedes by -- the

1 recall by several years, and since it doesn't refer
2 to Digitek, can we agree that this 2004 483 has
3 nothing to do directly with whether any consumer got
4 out-of-specification Digitek?

5 A. No. I would not say that.

6 Q. Why not?

7 A. I would say any time there is GMP
8 concern that affects -- potentially affects across a
9 system, I'm always concerned, as a quality
10 professional, that we could have released -- if it's
11 my company -- that we could have released defective
12 product.

13 Certainly, we are releasing, if it's
14 significant enough, adulterated product. Now let's
15 determine whether or not a defective product, as we
16 would define as out-of-specification, went out the
17 door.

18 I would take that 483 very seriously.

19 Q. Well, I'm not suggesting you wouldn't,
20 and I'm sure -- would you agree the FDA takes these
21 seriously?

22 A. I think that's their job, so I would
23 make that assumption.

24 Q. So if they had a concern about Digitek,
25 and found either GMP violations or

1 out-of-specification results for Digitek, it's
2 likely that they'd address it in this 483.

3 A. I don't know. You'd have to talk with
4 them.

5 Q. Tab 4 in your Appendix B was a
6 Complaint For Permanent Injunction.

7 Are you an expert at all on the legal
8 effect of a Complaint For Permanent Injunction?

9 A. No, I am not.

10 Q. Have you ever been sued?

11 A. No. Thank goodness.

12 Q. Have you ever sued anyone else?

13 A. Never will.

14 Q. Well, you might have a customer stiff
15 you. You might want to sue them for your fees.

16 A. I would never do that.

17 Q. You get it all up front?

18 A. No. The exact opposite. If I don't
19 understand that customer well enough that I know I'm
20 going to get paid, it's my fault.

21 Q. Okay. But you --

22 A. So I would not sue them. No.

23 Q. You don't know what the legal import of
24 this document is.

25 A. No, I don't.

1 Q. Do you know what a complaint is, just
2 an accusation?

3 A. I believe I do.

4 Q. Not -- not proof of what's contained
5 it?

6 A. Right.

7 MR. MILLER: Object to the form.

8 A. I believe that's correct, but I'm not
9 an expert on the subject.

10 Q. In Tab -- I already asked you that.

11 Your Reference 14 was Plaintiffs'

12 Exhibit 137. Okay?

13 And it's -- I'm not sure who drafted
14 it, but it's essentially a summary of an August 2006
15 GMP inspection.

16 Is that right?

17 A. Yes. It appears that.

18 Q. Is there anything in that document
19 about out-of-specification Digitek?

20 A. I'd have to look through it.

21 Q. Go ahead.

22 MR. MILLER: I object to form in that
23 it's misleading. Sometimes you say "specifically
24 Digitek," and sometimes "Digitek." So you need to
25 let him know --

1 MR. MORIARTY: What's the difference?

2 Q. Is the word "Digitek" in that document?

3 Did it talk about Digitek out-of-specs?

4 A. Repeat your question. I don't have to
5 look at -- I see you have it.

6 Q. What's the difference between "Digitek"
7 and "specifically Digitek"?

8 A. Can I give you an example?

9 Q. Because I'm going to get a mouthful
10 about, well, if they say it about Aprodine, it must
11 apply to Digitek.

12 I want to know if Digitek out-of-spec
13 is in that document. That's what I want to know.

14 A. In -- indirectly.

15 Q. Directly. Is Digitek --

16 A. No, not Digitek --

17 Q. -- out-of-spec in there?

18 A. I'm not trying to wordsmith it, but the
19 word "Digitek" does not appear in this document,
20 that I could see.

21 Q. Okay. Well, when you say indirectly,
22 show me what you're referring to.

23 Give me an example.

24 A. We'll take the first one.

25 "Failure to fully investigate errors.

1 All lab data not included with batch records.

2 Manufacturing deviations not always documented."

3 Well, that's a situation where you
4 don't know whether it includes Digitek or not, and
5 the assumption has to be, since there are so many
6 examples, that the system is out of whack, and that
7 you would have no way of assurance that if Digitek
8 had an issue, it would be part of the examples that
9 they looked at.

10 Q. Have you done anything to determine
11 whether, in fact, Digitek was ever determined to
12 fall into this broad heading?

13 A. The -- I don't need to do that.

14 Q. Why not?

15 A. Because when a quality system that cuts
16 through a company is found to be out of control, it
17 implicates all of the products. And certainly when
18 I looked through records, I would look specifically
19 for the name Digitek, and if I found it, I would try
20 to make note of it and try to understand if it was
21 one of the specific examples that were used.

22 If you say that the -- if you don't
23 have a system to report out-of-specifications, I'm
24 never going to see the -- unless I looked at the
25 hard data, you know, going through laboratory

1 records that don't appear in batch records, there
2 would be no way of me knowing that they occurred
3 unless I looked at them.

4 So by saying that I can't find them,
5 I'm saying that, you know, that Digitek is part of
6 that. I can't find if it did exist.

7 MR. KAPLAN: I'm going to move to
8 strike the last answer as not responsive to the
9 question that was asked. You were asked, did you do
10 anything to determine. Your answer was, I don't
11 need to do it. The question was, did you do
12 anything. Yes or no. Did you?

13 MR. MILLER: And that is an answer, yes
14 and no is not always required.

15 MR. KAPLAN: Did you do anything?

16 THE WITNESS: Did I do anything? Yes.
17 Did I --

18 MR. KAPLAN: Did you follow up on that?

19 THE WITNESS: I -- I followed up on --

20 MR. MILLER: Objection. Asked and
21 answered.

22 THE WITNESS: -- in that -- in that. I
23 had a limited amount of information that was given
24 to me.

25 When I see, let's say, a qualified

1 individual come up with example after example, and
2 find that there is significant holes in the system,
3 particularly where the information -- they're saying
4 the information is not processed, it's not even --
5 they don't even discover it. Then I have to make
6 the inference that it includes the entire population
7 of products, of which Digitek is part of that
8 population.

9 You don't know what you don't know.

10 MR. KAPLAN: So everything you're
11 saying is based on an inference.

12 THE WITNESS: It is not an inference.

13 MR. MILLER: Objection to form.

14 MR. KAPLAN: That's what you said.

15 THE WITNESS: No, I did not say --
16 well, if I said "inference," I used the wrong word.
17 I would say it's part of -- it would be -- do you
18 want me to explain?

19 MR. KAPLAN: I really don't.

20 THE WITNESS: Okay.

21 MR. KAPLAN: I really want you to
22 answer that question. That's why I moved to strike.

23 MR. MORIARTY: Let me get back on my
24 track.

25 Q. This is a -- the first column of this

1 Plaintiffs' Exhibit 137 is a statement out of a 483
2 observation or a warning letter; correct?

3 A. I believe that's correct.

4 Q. Which we established six hours ago, or
5 more, was not a final agency action of the FDA;
6 correct?

7 A. Correct.

8 Q. So would you concede that this may not
9 apply to Digitek, this observation?

10 A. Okay. It -- it -- could I concede that
11 there are -- there's a possibility that, for
12 whatever reason, a system breakdown only occurred
13 with the specific examples that they found? I would
14 say there's a possibility, not a high probability.

15 Q. Okay. But you are assuming this
16 applies to Digitek. Is that right?

17 MR. MILLER: Objection to form.

18 A. I'm assuming that it applies to
19 everything, because it is a system issue. It's like
20 you -- if you go to five places, only five places,
21 and you find people weren't trained, you make the
22 assumption. You're not going to go to every
23 single -- do a 100 percent inspection, if you will,
24 of every single position to find out if they're
25 adequately trained.

1 You have enough information to say the
2 training program is not in effect.

3 Q. Okay. So you're assuming it applies to
4 Digitek, is the short answer.

5 MR. MILLER: Object to form.

6 A. You say -- you say I'm assuming.

7 I'm saying that the system -- there's a
8 system issue. Digitek is affected by that system;
9 therefore, it does not have a reliable system and,
10 therefore, affects, or potentially affects, Digitek.

11 Q. But you haven't seen any direct proof
12 of this problem with Digitek, from this Exhibit 137.

13 A. No. I have not seen the name Digitek
14 associated as -- as an example with that.

15 Q. All right. And in just for this
16 example, "The failure to fully investigate errors,
17 all lab data not included within batch records,"
18 does not necessarily indicate that the final product
19 was outside its specifications, does it?

20 A. Quality -- I'll tell you how the a
21 quality assurance and myself --

22 Q. Yes or no.

23 A. You have to repeat it.

24 Q. No. I want to know -- I want to know
25 whether this specific observation, "Failure of the

1 quality unit to fulfill its responsibilities," is
2 the general statement. "Failure to fully
3 investigate errors, all lab data not included within
4 batch records," that doesn't necessarily mean the
5 finished product is going to be out of
6 specifications, does it?

7 MR. MILLER: Objection. Asked and
8 answered.

9 Q. Even for the specific product they're
10 talking about here.

11 Is that right?

12 A. Can I reread it again, please?

13 Q. Sure.

14 A. I have no specific examples that I know
15 of where the FDA has found that would fall under
16 this category, specifically to Digitek. This -- it
17 falls under this category because it's part of a
18 control system that affects the quality of Digitek
19 product.

20 Q. And my next question, which I would
21 like an answer to, is whether the failure to fully
22 investigate errors and all lab data not included
23 with batch records, that doesn't necessarily mean
24 that the finished product is out of specification.
25 Is that correct?

1 A. It sure -- it sure potentially
2 implicates it as a potential out-of-specification.

3 Q. Potentially.

4 A. Correct.

5 Q. But it doesn't necessarily --

6 A. No.

7 Q. -- follow as night does day.

8 A. Correct. That is correct.

9 Q. Your Tab or Reference 15 is Exhibit 25.
10 A February 1, 2007 warning letter.

11 Okay?

12 Does it say anything in there about
13 Digitek tablets being out of specification, or
14 equipment used to make Digitek being not qualified?

15 A. I'm going to have to read it.

16 Q. Fire away. Specifically.

17 A. I understand -- I understand your
18 question now.

19 If I can breeze through this, there are
20 no products specifically mentioned in this.

21 Q. Okay.

22 A. At least as I'm going through it.

23 Q. All right.

24 A. They talk about system failures.

25 Q. Your Reference 21 is Exhibit M-16 from

1 Susie Wolf's deposition.

2 Do you see that?

3 A. Yes.

4 Q. And it's a document about

5 Batch 80202 A; correct?

6 A. Yes.

7 Q. And a hold was put on that batch.

8 Is that right?

9 A. That is correct.

10 Q. Now, do you know whether that batch was
11 ever distributed to the market?

12 A. 802 -- 80202 A, bulk tablet was
13 released --

14 THE REPORTER: Sir, you have speak up,
15 and speak slowly.

16 THE WITNESS: Oh, I'm sorry.

17 Q. Talking to yourself is a bad idea.

18 A. I was talking to everybody. You just
19 didn't hear me.

20 The -- what I put down here, and I
21 believe it's accurate, is, "Bulk tablet lot was
22 released to fill and packaging, only later to be
23 placed on hold due to a tablet weight issue. They
24 indicated that this is one of the problem child."

25 This is grammatically incorrect, but --

1 so what -- what this implies is that they found out in
2 packaging that which they should have found out in
3 tableting. Okay? In other words, a product that is
4 out of weight should not -- or any defect, for that
5 matter -- should not be discovered in a subsequent
6 operation.

7 Q. But it was discovered and not released
8 to the market; correct?

9 A. It appears that way, yes.

10 Q. You won't find it on the recall list;
11 correct?

12 A. I'd have to compare it to the recall
13 list, but I would make that assumption.

14 Shall I give this back to you?

15 Q. In your references was number 26, which
16 is Exhibit M-14 from the Wolf deposition.

17 A. Yeah.

18 Q. It's an E-mail, and it says here,
19 "Connie," and it gives two batch numbers, "have
20 assays too low." Do you see that?

21 A. Yes.

22 Q. And then it gives numbers of 96.2 and
23 97.3 as the assay numbers; correct?

24 A. Um-hum.

25 Q. Are you familiar enough with the USP

1 monograph to know that those assays are well within
2 the specification?

3 MR. MILLER: Object to form.

4 A. The way I read this, they could put
5 100 percent. It is not what I'm looking at.

6 When somebody says, in management,
7 Susie Wolf says that the assays are too low, these
8 may or may not be accurate information. Something
9 is going on. You just don't say something is within
10 specification when, in fact, it's not. Only a
11 person who should be working for the competition
12 should be saying that.

13 And they are looking now at another
14 batch, 71004 A1, because, apparently, it's not being
15 implicated with a low assay. So that number, to me,
16 is immaterial. This is -- this is not somebody
17 who's saying the specification is, the USP states X,
18 this is -- this is -- and, therefore, this is Y,
19 and, therefore, it's out of specification, or it's
20 in specification.

21 Q. Do you know who came up with those
22 assay numbers?

23 A. No.

24 Q. So you don't know whether those are
25 from Actavis or not; right?

1 A. Whether they're -- no. I don't know
2 where those numbers came from.

3 Q. Do you know whether Mylan or UDL
4 subsequently had Celsis labs test any of those
5 batches?

6 A. No, I don't.

7 Q. Do you know, in fact, whether or not
8 those particular batches were out of specification,
9 by anybody's measurements?

10 A. Give me the batch numbers again,
11 please.

12 Q. 709 --

13 A. I'd like to look at them myself.

14 Q. Sure.

15 A. Okay. Please ask your question.

16 Q. Okay. My question was, do you know
17 whether or not these batches were ever tested as
18 actually out of spec by anyone?

19 A. No, I don't know if they were.

20 Q. In fact, do you know whether --
21 withdraw that last question fragment.

22 Okay. In your references was number
23 33. It was a Plaintiffs' Exhibit 172. It's an
24 E-mail at Actavis from Jisheng Zhu, J-I-S-H-E-N-G,
25 Z-H-U, in March of 2008.

1 Do you see that?

2 A. Yes.

3 Q. And he's referring to three impurities
4 in some Digoxin batch test.

5 Do you see that?

6 A. Yes, I do.

7 Q. Do you know whether, in fact, these
8 were investigated?

9 A. Were they investigated? I don't know.
10 I'd have to go back and research it.

11 No, I don't know if they were
12 investigated.

13 Can I read the statement again?

14 Q. Sure.

15 A. This appears to be self-explanatory.
16 Someone that said that they took a look at the
17 results, released data, and then all three lots
18 showed high impurities. It's quite simple.

19 Q. No. My question is: Do you know
20 whether these instances were investigated?

21 A. No, I do not know if they were.

22 Q. Do you know anything about whether the
23 impurities, if there were impurities, affected the
24 potency of any of these three lots?

25 A. I am not technically qualified to

1 answer that.

2 Q. Your Reference 45 is a 483 and some
3 associated data from 1999.

4 What was the specific relevance of a
5 1999 483 to your opinions in this case?

6 A. 45? I was looking for the -- any
7 repeat pattern.

8 Q. Okay. A repeat pattern of regulatory
9 issues?

10 A. Of GMP issues.

11 Q. And there is nothing in this 483, your
12 reference number 45 --

13 A. Yes.

14 Q. -- about Digitek, is there?

15 A. Can I read it one more time?

16 Well, the products are crossed out. I
17 would have no way of knowing.

18 Q. Well, just so you know, we didn't
19 redact Digitek out of it, because that's what the
20 litigation is about.

21 A. Okay. So my assumption is that none of
22 these are Digitek, that Digitek name does not appear
23 in this document.

24 Q. Okay. May I have that back, please.

25 Number 52, reference 52, is Plaintiff's

1 Exhibit 168. It's a packaging memo about why there
2 were two additional Digitek bottles in the
3 repackaging of 70924. Okay?

4 What was the significance of this to
5 your opinions in this case?

6 A. Okay.

7 Q. If any.

8 A. I did have some.

9 The -- this memo, or whatever it is, is
10 issued by Scott Talbot. It is undated. It is
11 unapproved.

12 What that immediately tells me, forget
13 about the content, per se, he is trying to explain
14 why something happened.

15 An unapproved, undated document is --
16 is not a -- does not provide me evidence that an
17 adequate investigation was done. Here I see what
18 looks like some logical accounts of what the person
19 did, and trying to explain why -- why they had extra
20 tablets as a result of something that should have
21 had less tablets.

22 So I'd say -- I looked at this
23 immediately from a GMP compliance standpoint. How
24 could you possibly issue a memo that's not dated,
25 not signed, and should be part of an investigation.

1 It's horrendous.

2 Q. Well, it doesn't say there are extra
3 tablets, does it? It says there are extra bottles.

4 A. Extra bottles, which means extra
5 tablets.

6 Q. Well, if the fill machine is off by a
7 tablet even every couple bottles, it is going to
8 fill additional bottles; correct?

9 A. If it is off by a fraction -- I'm
10 sorry. Could you repeat that?

11 Q. The fill machine is putting maybe 100
12 tablets in a bottle. I think for this batch, I
13 think they were all 100. I don't remember what the
14 bottle count was.

15 A. Yeah.

16 Q. But even if it is off by one tablet
17 every couple of bottles you are going to get extra
18 bottles, aren't you?

19 A. Using your assumption, if there is --
20 if the original process put more tablets in than the
21 labeled amount, and then the subsequent process put
22 the correct amount in, then one would assume that
23 the reasons for extra units is due to the fact that
24 you put too much in to begin with.

25 Q. And that can happen; right?

1 A. That can certainly happen.

2 Q. Okay. Because these filling machines
3 are not accurate enough to regularly put in 100
4 tablets per bottle, through a run as large as this;
5 correct?

6 A. Correct. I would like to offer my
7 experience, though.

8 I have found very, very few instances
9 where a company put too many tablets in. In fact, I
10 have seen quite the opposite, and I can provide
11 examples, if you like.

12 Q. Well, that's not the issue with this.
13 I think the point you were making is --

14 A. GMP.

15 Q. -- to you this is a GMP issue about is
16 this signed, authorized, etcetera.

17 A. Because the value, even if it were a
18 very logical explanation, the value of it is nil.
19 It is a gross violation of GMP. And how that
20 document could have been created and distributed,
21 and how anybody would have received it and not
22 kicked it back to the original person to make sure
23 it wasn't signed or dated, is beyond me.

24 It's a total -- talk about a breakdown,
25 this is a significant breakdown.

1 Q. Okay. And that is a classic example of
2 how a -- in your view, a GMP violation may not
3 affect the identity, purity, or potency of the
4 tablets in the bottle; right?

5 A. No. No. I don't agree with that at
6 all.

7 I know nothing about that. They had an
8 overage. Everybody would have expected that they
9 lost tablets. In other words, when they are doing
10 their inspections, they are going to see tablets,
11 perhaps, that have specks on them, that have chips
12 on them. Every time you handle a tablet you will
13 abuse the tablet and ultimately end up with,
14 perhaps, cosmetic issues, but -- content issues,
15 too, if it has a chip.

16 So one would logically assume as part
17 of the ongoing production and handling of that, that
18 that number would dwindle.

19 There are no records in the 100 percent
20 inspection that even -- even referred to were there
21 any other defects found. All it refers to is that
22 there were 20 total from that particular batch.

23 So it is void of information. And I
24 make no assumptions on a letter that's not signed.
25 I -- I would say that that is a classic GMP issue,

1 of which I wouldn't respond to the content because
2 it is unofficial.

3 Q. Okay. I am not asking about the
4 content of the memo.

5 You wouldn't use your reference 52 as a
6 GMP violation that proves that the tablets were out
7 of specification, would you?

8 A. Let me see how I used it, please.

9 I'm having a hard time finding those
10 small -- 53. Here's an example -- ask your
11 question. I'm sorry.

12 Q. I want to stick with your reference 52.

13 You wouldn't use this memo as proof
14 that the tablets in these bottles were outside the
15 USP specifications, would you?

16 A. I would use that -- I -- I couldn't use
17 that as an example. What it tells me, though, is
18 things are so lax associated with that particular
19 process, I now question the competency of the people
20 that are even writing and reading these things.

21 So if I -- if I don't feel confident in
22 the person, now I really have an issue. It is a
23 bigger issue than the content in that explanation.

24 Q. Your reference 60 is to the "all
25 product recall" that followed the Digitek recall.

1 Is that correct?

2 It's a press release.

3 Here you can look at it. Right here.

4 A. Yes. Yes.

5 Q. Are you aware --

6 A. I cut and pasted that.

7 Q. Are you aware that that recall was not
8 to the consumer level?

9 A. I believe that I was aware of that,
10 yes.

11 Yes, I was aware.

12 MR. MORIARTY: All right. The next
13 thing I want to get into is his report.

14 Off the record, please.

15 THE VIDEOGRAPHER: Stand by. We are
16 going off the record. The time is 5:01.

17 (Exhibit 47, Expert Opinion of Mr.
18 Kenny and CV is received and marked for
19 identification.)

20 THE VIDEOGRAPHER: We are back on the
21 record. The time is 5:14 P.M.

22 Q. Mr. Kenny, I had marked as Exhibit 47 a
23 50-page document.

24 Do you see this?

25 A. Yes.

1 Q. And the beginning of it is your report
2 in this case.

3 Is that right?

4 A. Correct.

5 Q. Also contained within Exhibit 47 is --
6 are a number of appendices.

7 Is that right?

8 A. Well, at the tail end.

9 I think it started with my resume.

10 Q. Right. Here is the list of appendices
11 at page 36.

12 Is that correct?

13 A. Yes.

14 Q. And then the appendices are your CV.

15 A. Right.

16 Q. B is the references. C is a chronology
17 of lot 70924.

18 Is that right?

19 A. Yes.

20 Q. D is a press release of the Digitek
21 recall.

22 Is that correct?

23 A. Yes.

24 Q. And E is what I call the all products
25 recall press release.

1 Is that right?

2 A. Yes.

3 Q. And then F is a summary of FDA
4 observations and events.

5 A. That's right.

6 Q. Do you know who drafted the summary?

7 A. I did.

8 Q. Summary of FDA observations and events?

9 A. Yes. I went through the observations
10 and tried to put them into layman's terms,
11 hopefully, or more easily understood terms.

12 Q. Okay. Now, we issued a notice for your
13 deposition.

14 Did you actually see the notice?

15 A. Yes, I did.

16 Q. And it asked you to bring a certain
17 group of documents, did it not?

18 A. Yes.

19 Q. Let me go through some of the ones that
20 I have questions about.

21 Number 2, "All correspondence,
22 communication between the witness or anyone acting
23 on the witness' behalf, and attorneys representing
24 Plaintiffs in this Digitek litigation."

25 Did you bring all the correspondence?

1 A. No. I -- I didn't have the time to do
2 it.

3 Q. You are going to supply it?

4 A. Absolutely. I'm obligated. I
5 personally feel obligated.

6 Q. Has -- is Sal signatory to any of the
7 correspondence with the Plaintiffs' lawyers?

8 A. What do you mean by "signatory"?

9 Q. Signed.

10 A. No. His name -- his signature is
11 nowhere.

12 Q. Has Sal billed for time related to the
13 Digitek litigation?

14 A. Yes, he has.

15 Q. Does he bill you or the Plaintiffs'
16 lawyers?

17 A. He, in essence, bills me, and then I
18 put it into the -- I put it into an invoice which
19 goes to the Plaintiffs' lawyers.

20 Q. Are you doing any other litigation
21 consulting besides the Digitek litigation?

22 A. I have never done it, and I'm not doing
23 it.

24 Q. Okay. This is the only one?

25 A. This is it.

1 Q. When you consult with pharmaceutical
2 clients, do you bill them by the hour?

3 A. I try not to bill by the hour, per se.
4 What I try to do is no greater than,
5 because I know what it's like to receive a bill. So
6 what I do is I try to very carefully craft what my
7 deliverables are. I craft exactly how I think I am
8 going to get to that deliverable, how much time it
9 is going to take.

10 I try to put some allowance in there
11 for invariably stuff happens, but I put very little
12 of that in. And then I tell them that I am going to
13 bill by the hour but it will not exceed that number.
14 And that's the way I have done 90 percent of my
15 billing. This is an exception.

16 Q. And what do you bill pharmaceutical
17 clients per hour?

18 A. Well, it depends upon -- I am going on
19 an audit to Wales. I am going to bill them 300
20 and -- about \$300 an hour.

21 Q. Do you bill any of your pharmaceutical
22 clients \$430 an hour?

23 A. You mean like -- no. No is the answer.

24 Q. Item 3 on what we asked you to bring
25 is, "All other documents prepared by the attorneys

1 for the Plaintiffs and sent to you."

2 Did you bring those?

3 A. No, I did not bring them with me.

4 Q. You are going to produce those?

5 A. Yes. I am going to produce exactly
6 what you asked for.

7 Q. Do you have a retainer agreement with
8 them?

9 A. I received a retainer.

10 Q. Do you have a retainer agreement?

11 A. I don't even know what that is.

12 Q. A fee agreement.

13 A. A fee agreement? Oh, yes. Yes.

14 Q. Is that among the correspondence that
15 you will produce?

16 A. I wasn't realizing that was part of it,
17 but I will be glad to produce that.

18 So it also includes any business
19 dealings. Is that it?

20 Q. It does.

21 A. Okay.

22 Q. It says here -- number 6, all bills
23 that you've rendered to the attorneys and law firms
24 in connection with this.

25 A. Yes, I do. Since I knew I couldn't do

1 it, I didn't go through it with a fine-tooth comb to
2 determine how to get it.

3 Q. And --

4 A. Which I will, though. I will go
5 through that with a fine-tooth comb.

6 Q. And I think you said you issued one
7 bill?

8 A. That's right.

9 Q. For what period of time did that cover?

10 A. That covered up until, I don't know,
11 March -- March sometime.

12 Q. When is the next bill going to go out?

13 A. The next bill is going to go out almost
14 immediately. But I was waiting to get the money
15 before I sent a second bill.

16 I don't want to say money is not an
17 issue, but it's not -- it's not my driving force.

18 Q. I understand.

19 Number 9, everything that you reviewed
20 that indicates that Plaintiffs ingested defective
21 Digitek.

22 What did you bring responsive to number
23 9?

24 A. Would you repeat that again?

25 Q. It says --

1 A. I haven't read it in that detail.

2 Q. It says, "Everything the witness
3 reviewed that indicates that the Plaintiffs ingested
4 defective Digitek."

5 A. What did I bring to where? As part of
6 the --

7 Q. Well --

8 A. -- reference information and stuff that
9 I read?

10 Q. You were supposed to bring any
11 documents that indicated that Plaintiffs, people,
12 consumers --

13 A. Yeah.

14 Q. -- who have sued my client, actually
15 took defective Digitek.

16 A. I haven't even thought about that
17 question. I would have to think about it, determine
18 what -- what I've sent to them and then, basically,
19 formulate whether or not it falls into that
20 category.

21 Q. Did you read any medical literature?

22 A. No, I have no interest in it.

23 Q. Now, you mentioned Mr. Kowalski, or
24 someone else --

25 A. John Kowalski.

1 Q. John Kowalski. Has he billed any time
2 to the Digitek work?

3 A. I have no idea. I haven't talked to
4 John in years.

5 We know each other through a lot of
6 dealings years back.

7 Q. And to whom do you send your Digitek
8 bills when you send them?

9 A. I send them through Meghan, which goes
10 to some -- I don't know, somehow they pay it.

11 Q. Okay.

12 MR. KAPLAN: So you haven't been paid?

13 THE WITNESS: No. We did get paid two
14 days -- we received a check either Monday or Friday.
15 I don't recall.

16 MR. KAPLAN: You just said you hadn't
17 been paid.

18 THE WITNESS: No. No. No. I said I
19 got -- I did receive a check. And I said now --

20 MR. KAPLAN: How much was it?

21 MR. MILLER: Objection. Asked and
22 answered.

23 THE WITNESS: To be honest, I am not
24 trying to avoid it, the money is not that much of an
25 issue to me. I just kind of throw more money in the

1 bank. It's not why I do this job. I don't do it so
2 that I can count up all this money. I do it because
3 I enjoy it, and I'm helpful, and I get paid well in
4 all of my assignments.

5 Q. Does Sal have an ongoing role, or do
6 you contemplate one in the Digitek consultation?

7 A. No. I have no intentions of involving
8 him at all. It would be inappropriate at this
9 point.

10 Q. In 2010, to date, how much of the
11 income of SpyGlass is related to the Digitek
12 litigation work versus your pharmaceutical
13 consulting?

14 A. Well, I have contracts for -- I figure
15 100,000, I have another contract for 40,000, so
16 that's 140, I'll get -- I am going on a proposal
17 tomorrow and I'm going to get it, and that will be
18 billed at somewhere between 250 and \$300 an hour,
19 depending on the work, because it is not as
20 technically challenging, so I like to keep it lower
21 if it is not using my -- my -- my strategic
22 abilities.

23 So having said that, right now, based
24 upon what I know I'm going to get, it -- the 25,
25 whatever it is, thousand dollars represents one -- I

1 don't know, one quarter, or something like that.

2 MR. KAPLAN: I'm -- I'm going to move
3 to strike that last answer.

4 The question was simply to date, not
5 what you're going to get, not what --

6 THE WITNESS: But I have contracts.

7 MR. KAPLAN: It was, to date, what
8 percentage of your income has been represented by
9 your consulting. It is to date.

10 MR. MILLER: He is attempting to answer
11 that.

12 A. Well, I got 22, I got -- to date
13 probably half of that one. So to date 75,000, so
14 this is one quarter. If I am getting 100,000, this
15 is one quarter.

16 Q. Okay. And what percentage of your time
17 is the Digitek litigation versus your consulting
18 work?

19 A. The time? Over the last several
20 months, it's been very high. Higher than I
21 anticipated. And it represents probably half.

22 Q. Okay. And how many times before you
23 wrote your report did you have in-person meetings
24 with the Plaintiffs' lawyers?

25 A. Before I wrote the report? I had no

1 in-person meetings.

2 Q. All the communication was --

3 A. Was on the phone.

4 Q. -- phone or E-mail?

5 A. Yes.

6 Q. Did you have any video conferences with
7 them before you wrote your report?

8 A. No.

9 Q. Did you meet with them in person
10 regarding the revisions to your draft reports?

11 A. I met with them once regarding the
12 revisions.

13 Q. When was that?

14 A. Oh, a month ago, something like that.

15 Q. And with whom did you meet before today
16 to prepare for your deposition?

17 A. To prepare for my deposition, I met
18 with nobody.

19 Oh, you mean met with physically?

20 Q. Yeah.

21 A. Before -- well, before today, I met
22 last night.

23 Q. With whom?

24 A. With Meghan.

25 Q. For how long?

1 A. You mean how long did we talk about
2 work, or how long did I see her?

3 Q. How long did you spend preparing for
4 your deposition?

5 A. You mean with her or without her?
6 I have to understand what you are
7 talking about.

8 Q. With Meghan.

9 A. Oh, with Meghan? I don't know. An
10 hour.

11 Q. Obviously, you spent time reviewing
12 documents again.

13 A. Again, I went back and reread, you
14 know -- reread this, took a look at some of the 43s,
15 tried to -- yeah. Took a look at those kinds of
16 things.

17 Spent very little time with Meghan.
18 We did go to dinner together, but that
19 was all casual.

20 Q. And, at the outset of this project,
21 what was your understanding of what your function
22 was or your role?

23 A. My role was to determine whether or not
24 this company was in compliance with GMPs over a
25 certain period of time, which turned out to be 2004

1 to 2009, and to determine whether or not products
2 that were violative were released.

3 Q. I understood your answer except for one
4 word.

5 When you said "violative," do you mean
6 violative of cGMP regs?

7 A. cGMP regs, yes, and whether or not
8 defective product was released.

9 Q. When you say "defective," what do you
10 mean BY defective?

11 A. Product which does not meet finished
12 product specification requirements or stability
13 requirements.

14 Q. I'm sorry. Defective, in your mind,
15 means doesn't meets stability requirements or what
16 was the other element?

17 A. Does not meet product specification
18 requirements.

19 MR. KAPLAN: You said "finished
20 products."

21 A. Finished. Products specif --I
22 understand that you -- I am going to correct myself
23 and say product specifications.

24 Q. Okay. And what product specifications?

25 A. Any specifications that would implicate

1 that a defective product was in the field.

2 So it could be, let's say, content
3 uniformity, or bulk specification testing,
4 tableting, packaging, finished product sampling,
5 stability testing, any point along the way which
6 would also implicate or -- or you would determine
7 that defective product either was or highlight that
8 it could have been released.

9 Q. Okay. So is it your opinion that
10 product that didn't meet stability requirements for
11 Digitek was released to consumers?

12 A. You are going to have to repeat that
13 question.

14 Q. Do you have an opinion, to a
15 probability, about whether Digitek that didn't meet
16 the stability requirements reached consumers in the
17 recalled batches between 2006 and 2008?

18 A. Stability, I have no -- I saw no data
19 to suggest that that would have been an issue.

20 Q. Do you have an opinion, to a
21 probability, that product that did not meet the USP
22 finished product specifications made it to consumers
23 between 2006 and 2008?

24 A. I think product did reach the consumer
25 s that is out of specification to a reasonable

1 degree of certainty.

2 Q. Now, I asked you earlier how much
3 product, how far out of spec, all of those things,
4 and you had no opinions to quantify it; correct?

5 A. Correct.

6 Q. All right. So what is the basis for
7 your opinion that product not meeting the USP
8 finished product specifications made it to
9 consumers?

10 A. Because of there are so many systemic
11 system issues, that it's -- it's difficult for me to
12 believe that product didn't get through. And in my
13 heart of hearts that's what I believe.

14 Q. So if I had to summarize the
15 methodology of your analysis for that answer that
16 you just gave me, you look at the cGMP violations,
17 and you conclude or opine that it is, therefore,
18 difficult for you to believe that
19 out-of-specification product didn't get through?

20 MR. MILLER: Object to form.

21 Q. You can answer.

22 A. You are going to have to repeat it,
23 please.

24 MR. MORIARTY: Read it back, Carol,
25 please.

1 (Requested portion is read.)

2 A. I would say that's accurate.

3 MR. MILLER: It is after 5:30, Matt.

4 Is this is a good time to wrap it up?

5 MR. MORIARTY: This is probably the
6 perfect breaking point.

7 MR. KAPLAN: Before we go off the
8 record, and I know that Matt has not finished his
9 questioning -- I'm Harvey Kaplan, and I represent
10 Mylan.

11 THE WITNESS: I'm sorry. What?

12 MR. KAPLAN: I represent Mylan, the
13 other Defendant --

14 THE WITNESS: Yes.

15 MR. KAPLAN: -- in the litigation.

16 So I haven't had a chance to examine
17 you. I will have a chance when you come back.

18 There was a notice sent for your
19 deposition here today, and you said you saw the
20 notice.

21 THE WITNESS: Yes, I did.

22 MR. KAPLAN: And it -- it lists 13
23 categories of documents that you were requested to
24 bring.

25 THE WITNESS: I'll assume that's

1 correct.

2 MR. KAPLAN: And I want you to please,
3 before your next deposition, not only carefully
4 review those 13 categories, but please bring those
5 documents with you, because we will surely ask you
6 for all of those things. Okay?

7 THE WITNESS: Understood.

8 MR. MILLER: And just to be clear,
9 Harvey, when you said Matt was finished asking
10 questions --

11 MR. KAPLAN: I said he was not
12 finished.

13 MR. MILLER: Not finished. Okay. I'm
14 sorry, Harvey.

15 MR. KAPLAN: I said Matt has not
16 finished. I've never gotten to begin my questioning.

17 MR. MORIARTY: I have not finished.

18 MR. MILLER: I totally understand. And
19 I will have questioning, as well, so...

20 MR. KAPLAN: Good. Then we shall meet
21 again another day soon, I presume. Probably the
22 same place.

23 THE WITNESS: This place is fine with
24 me.

25 MR. KAPLAN: If that's okay.

1 MR. MORIARTY: All right. Off the
2 record.

3 THE VIDEOGRAPHER: Stand by. We are
4 going off the record. The time is 5:35 P.M. This
5 is the end of tape number 6.

6 (Proceedings concluded at 5:34 p.m.)

7 J U R A T

8

9 I DO HEREBY CERTIFY that I have read
10 the foregoing transcript of my deposition testimony
11 and I certify that is it true and correct to the
12 best of my knowledge.

13

14

15 Mark G. Kenny

16

17 SWORN AND SUBSCRIBED

18 BEFORE ME ON THIS

19 DAY OF 2010

20

21 Notary Public of the State of

22

23

24

25

1 ATTACH TO DEPOSITION OF: Mark G. Kenny
2 IN THE MATTER OF: In Re: Digitek Product Liability
3 Litigation

4 DATE TAKEN: June 29, 2010

5 E R R A T A S H E E T

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DATE and SIGNATURE:

1 CERTIFICATE

2

3 I, CAROL ANN SHEPARD, a Certified Court
4 Reporter of the State of New Jersey, License No.
5 30X100101900, do hereby certify that prior to the
6 commencement of the examination, MARK G. KENNY was
7 duly sworn by me to testify the truth, the whole
8 truth and nothing but the truth.

9 I DO FURTHER CERTIFY that the foregoing
10 is a true and accurate transcript of the testimony
11 as taken stenographically by and before me at the
12 time, place and on the date hereinbefore set forth.

13 I DO FURTHER CERTIFY that I am neither
14 a relative nor employee nor attorney nor counsel of
15 any of the parties to this action, and that I am
16 neither a relative nor employee of such attorney or
17 counsel, and that I am not financially interested in
18 the action.

19

20

21

22 _____
Certified Court Reporter of the State of New Jersey

23

24 Dated: July 2, 2010

25

Mark Kenny, Volume II

Videotaped

February 16, 2011

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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

MDL NO. 1968

IN RE: DIGITEK PRODUCT)CONTINUED
LIABILITY LITIGATION)VIDEOTAPED DEPOSITION
)OF:
)MARK G. KENNY

 X
 VOLUME II

TRANSCRIPT of the stenographic notes of
The proceedings in the above-entitled matter, as
taken by and before JANE D. WATSON, a Notary Public
of the State of New York, held at the office of
Harris Beach, 100 Wall Street, New York, New York
10005 on Wednesday, February 16, 2011, commencing at
9:50 a.m.

1 A P P E A R A N C E S:

2

3 MOTLEY RICE

4 28 Bridgeside Boulevard

5 Mount Pleasant, South Carolina 29464

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7 Counsel for Plaintiffs

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11 Kansas City, Missouri 64108-2613

12 BY: HARVEY L. KAPLAN, ESQ.

13 Counsel for Mylan

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15 TUCKER, ELLIS & WEST

16 515 South Flower Street, 42nd Floor

17 Los Angeles, California 90071

18 BY: MICHAEL ANDERTON, ESQ.

19 Counsel for Actavis

20

21 ALSO PRESENT:

22 Chris Martin, Videographer

23 Peter Cooper, Videographer in training

24 Rick Fern, Esq. (in a.m.)

25

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I N D E X

WITNESS

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IDENT.

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1 THE VIDEOGRAPHER: Good morning.
2 We're on the record. Today's date is
3 February 16, 2011, and the time is 9:50 a.m.
4 This is the continuation of the videotaped
5 deposition of Mark Kenny. The caption on
6 this case is In Re: Digitek Product
7 Liability Litigation. Case number -- I'm
8 sorry -- MDL number 2:09-CV-121. Case filed
9 in the U.S. District Court, Southern
10 District of West Virginia, Charleston
11 Division. We're at the office of Harris
12 Beach, 100 Wall Street, New York, New York.
13 This deposition was noticed by Attorney
14 Matthew Moriarty of the firm Tucker, Ellis &
15 West. The videographer is Chris Martin.
16 The court reporter is Jane Watson.

17 At this time, will Counsel please
18 introduce themselves for the record.

19 MS. CARTER: Meghan Carter for the
20 Plaintiffs.

21 THE WITNESS: Mark Kenny.

22 MR. KAPLAN: I'm Harvey Kaplan, Shook,
23 Hardy & Bacon for Mylan.

24 MR. ANDERTON: Michael Anderton,
25 Tucker, Ellis & West for the Actavis

1 defendants.

2 THE VIDEOGRAPHER: At this time, the
3 court reporter will swear in the witness.

4 M A R K K E N N Y, called as a
5 Witness, having been duly sworn by a Notary
6 Public, was examined and testified as follows:

7

8 EXAMINATION BY MR. KAPLAN:

9 Q. Good morning, Mr. Kenny.

10 A. Good morning.

11 Q. I think we met when your deposition
12 was taken on June 29 of last year, June 29, 2010 in
13 Newark, New Jersey, right?

14 A. Correct.

15 Q. At that time, you were examined by
16 Mr. Moriarty on behalf of Activas, right?

17 A. That's correct.

18 Q. He took pretty much the full day, so I
19 didn't have a chance to ask you questions, and today
20 is my opportunity to examine you on behalf of my
21 client, Mylan.

22 A. I understand.

23 Q. How are you doing?

24 A. I'm doing well, thank you.

25 Q. All right. Good. I know that you had

1 recent Achilles heel surgery, and we're sympathetic
2 to your situation. And as I told you, if you need
3 breaks throughout the day, all you need to do is say
4 that you need a break and we'll do that. Okay?

5 A. Thank you. It's much appreciated.

6 Q. All right. Just as you came to the
7 deposition on June 29, 2010 prepared to give your
8 opinions in this case -- you did?

9 A. Yes.

10 Q. You came prepared at that time, didn't
11 you?

12 A. Yes.

13 Q. And you are today prepared to give
14 opinions in this case; isn't that right?

15 A. Yes, I am.

16 Q. And all the work that you did in
17 preparation for any opinions that you will offer in
18 this case are contained within your report which was
19 dated June 15, 2010?

20 A. That is correct.

21 Q. And that report is in front of you?

22 A. That is correct.

23 Q. That -- that has all of your opinions,
24 right?

25 A. That is correct.

1 Q. You stand by that report?

2 A. Yes, I do.

3 Q. Or -- or is there anything you want to
4 withdrawal or modify?

5 A. I stand by the report.

6 Q. Stand by the report. Okay. And have
7 you done any further work since June 15, 2010 with
8 respect to --

9 A. Yes, I have.

10 Q. What have you done?

11 A. I've looked at some of the Mylan
12 exhibits again, I reviewed them.

13 Q. Why?

14 A. To familiarize myself with the
15 documents, refamiliarize, since it was a long time
16 ago that I reviewed it.

17 Q. What -- what Mylan exhibits did you
18 look at?

19 A. I have all of the Mylan exhibits here.

20 Q. Okay. But -- but I'm interested in
21 particularly what is it that you looked at and --

22 A. Well, I'd have to pull it and show you
23 what --

24 Q. Well, why don't you pull it and show
25 me what you looked at.

1 A. Okay. The vast majority of them are
2 ones that are referenced in my report. One of the
3 issues if you --

4 Q. Just -- there's -- there's a simple
5 question, and I'm going to ask you -- we'll get
6 through this a lot faster. Don't -- don't go off
7 and give me narrative answers, just concentrate on
8 the question I ask, okay?

9 A. I understand.

10 Q. So my question is -- here's the simple
11 question: You said that since your deposition was
12 taken on June 29, 2010, you reviewed some additional
13 Mylan documents?

14 A. That's correct.

15 Q. And my question is which documents did
16 you review, have you reviewed, since June 29, 2010?
17 That's all I want you to do is identify those.

18 A. They're in this particular binder.

19 Q. All right. Tell me which Mylan
20 exhibits you have reviewed since your deposition was
21 taken on June 29, 2010.

22 A. I can go through them?

23 Q. Certainly.

24 A. Okay.

25 Q. Just tell me which they are.

1 A. What additional ones?

2 Q. Yes.

3 A. Which ones -- see, the -- the
4 difficulty, if I can explain something, is that
5 between the original deposition and today, I don't
6 have the original copies that I reviewed that I
7 submitted. So I went back to the computer database
8 for Mylan and I went through to see if any of them
9 were germane to my opinion. And at that particular
10 point, I made copies of those and probably copies of
11 those -- a couple that were in addition to. So,
12 anyway, going through this -- are you ready?

13 Q. Yes.

14 A. M55.

15 Q. You're referring to the exhibit M55
16 from previous depositions?

17 A. Right.

18 Q. Let me see that. M55 is an e-mail
19 from Lee Radtke to Chuck Koons dated December 13,
20 2006; is that correct?

21 A. I believe -- I'm sure you're right.

22 Q. Okay. You reviewed -- you reviewed
23 that -- that exhibit?

24 A. Yes.

25 Q. Okay. And what, if anything, did

1 that --

2 A. This changed nothing, nothing at all.

3 Q. Just so we got a clean record on this.
4 You reviewed exhibit M55, the e-mail from Lee Radtke
5 to Chuck Koons dated --

6 A. Dated December 13, 2006.

7 Q. But that did nothing to change your
8 opinion --

9 A. Not in the least bit. Not in the
10 least bit.

11 Q. Didn't enlighten you in any regard?

12 A. The only -- I would say the thing that
13 enlightened me is that it reconfirmed when I had
14 stated that they did not do a comprehensive audit.
15 And he says in here, Chuck Koons, says we did a
16 system audit, I just don't think they could handle
17 it right now. But when I read the original report,
18 it was very clear to me that it did not represent
19 what the industry referred to as a comprehensive GMP
20 audit nor would it be in accordance to the procedure
21 that they had, which I did read.

22 Q. Did the FDA do comprehensive GMP
23 audits of --

24 A. I can't tell you whether it's
25 comprehensive or not. I will tell you they looked

1 in a lot of areas.

2 Q. A lot of times?

3 A. A lot of times.

4 Q. As many as 12 inspections between 1999
5 and 2008, correct?

6 A. Okay. If that's the number, I believe
7 you.

8 Q. Over a period of 182 days?

9 A. Yes.

10 Q. Is that right?

11 A. If you say so. I'll agree with that.

12 Q. You don't have any reason to disagree
13 with it?

14 A. No, I have no reason to disagree with
15 you.

16 Q. You would agree with me that the FDA
17 extensively audited Actavis over a nine-year period?

18 A. They inspected them, but yes.

19 Q. And audited them?

20 A. Well, they don't use the term "audit."

21 Q. Extensive inspections?

22 A. Yes.

23 Q. GMP inspections?

24 A. Correct.

25 Q. In fact, it's GMP or good

1 manufacturing practice regulations are the FDA's
2 regulations?

3 A. They are -- I -- I suppose you could
4 say that, yes. They are codified in the CFR.

5 Q. And they are what you would refer to
6 as expertly drafted law, right?

7 A. GMPs, yes, I believe that.

8 Q. All right. What is the next Mylan
9 document that you reviewed since your deposition was
10 taken on June 29, 2010?

11 A. M53 (handing).

12 Q. Exhibit M53 from a previous deposition
13 which you have just handed me, is a e-mail from Lee
14 Radtke to Chuck Koons dated October 13, 2006. And
15 is the highlighting yours?

16 A. Yes, every highlighting in here would
17 be mine.

18 Q. You've -- you've highlighted an e-mail
19 below from Chuck Koons to Lee Radtke, you've
20 highlighted the sentence that says, "We were already
21 scheduled to do an on-sight audit on 11/8 and 11/9,
22 and we're trying to get a status report on this
23 prior to our visit." That's the only thing that you
24 highlighted in 53, right?

25 A. That's correct.

1 Q. What -- what was the significance of
2 this to you?

3 A. Well, I had earlier wondered why it
4 wasn't scheduled and any -- any information that I
5 looked at what -- what referred to the audit either
6 explaining why -- why it was going to occur or why
7 it didn't occur was notable to me.

8 Q. Okay. And -- and how did this exhibit
9 M53 enlighten you?

10 A. It had no effect whatsoever on my
11 opinion.

12 Q. Okay. All right. And by the way,
13 when you -- since your deposition was taken on
14 June 29, 2010, did you review these additional Mylan
15 documents at one time, over a period of time? Tell
16 me how that occurred.

17 A. I did it -- I started two days before
18 the first scheduled deposition for 2009.

19 Q. 2009?

20 A. 2010. In other words, this calendar
21 year. So I looked at it in --

22 Q. We're now in 2011.

23 A. Eleven, rather, I'm sorry. In 2011, I
24 went back to review to familiarize myself, then I
25 realized I didn't have a lot of documents that I

1 felt were missing, and I went back to the Crivella
2 database and I picked out some procedures or some
3 documents including only these that are here. This
4 is it. (Indicating.) This is 100 percent
5 comprehensive (indicating).

6 Q. And over a period of -- you did this
7 review over a period of days, one day --

8 A. A period of two days.

9 Q. Two days? Okay. And that was --

10 A. But the -- can I explain that though,
11 if I may?

12 Q. Just try to answer my questions and
13 we'll get along. So I just want to understand what
14 you did, how much time you spent, why you did it,
15 what you looked at. So what you're telling me is
16 that your deposition had been scheduled earlier in
17 2011, right?

18 A. Correct.

19 Q. Two days before your deposition had
20 been scheduled, you -- you started looking at Mylan
21 documents?

22 A. Correct. I -- I went to seek out
23 documents to refamiliarize myself with the
24 references in the report. And then I found out I
25 didn't have those documents, then I went back into

1 the database for Mylan because I knew that the next
2 deposition was going to be focused on Mylan, and I
3 started looking at the documents and the numbers and
4 I made copies of anything that looked even remotely
5 close to the subject that I had put into my report.

6 Q. Okay. And how long did you spend
7 reviewing the Mylan documents?

8 A. I spent a day and a half printing the
9 documents and finding them. I spent another prior
10 to that, probably two hours reviewing the documents.

11 Q. So it took you a day and a half to
12 find the documents that are in this notebook in
13 front of you?

14 A. Right. I was panicking, so to speak.

15 Q. Okay. So it was two days before your
16 deposition was scheduled, you were panicked?

17 A. Yes.

18 Q. Because you knew I was going to be
19 asking you questions.

20 A. Correct.

21 Q. About Mylan?

22 A. Right.

23 Q. And you said, gosh, I got to go back
24 and beef up here, right?

25 A. Beef up is not the right term. I have

1 to refamiliarize myself with the basis of my
2 opinion.

3 Q. Okay. And so that was the purpose?

4 A. Correct.

5 Q. And it took you a day and a half to
6 find the documents and print them, right?

7 A. Approximately.

8 Q. And you -- you charged for -- for
9 that, right?

10 A. I have not charged for it. I'm --

11 Q. It's to be billed?

12 A. Yeah, yeah. But I'm not sure exactly
13 what the bill is going to be.

14 Q. So a day and a half, is that 12 hours?

15 A. That's 12 hours, yeah.

16 Q. Okay. At \$430 an hour?

17 A. Yeah. It's actually much more than
18 that, but I will not bill because I feel somewhat
19 culpable perhaps in not having these documents.

20 Q. So a day and a half to find the
21 documents and print them, and then two hours to
22 review them?

23 A. Approximately, yeah. And that
24 maybe --

25 Q. So the two hours is also at \$430

1 dollars an hour, right?

2 A. That's correct.

3 Q. By the way, \$430 an hour, is that the
4 highest billing rate that -- that you have on any
5 matter that you -- you're working on?

6 A. The highest billing rate -- when it's
7 a rate, yes.

8 Q. And I believe you testified previously
9 when your deposition was taken on June 29, 2010 that
10 you worked for various clients at \$250 an hour?

11 A. Two -- over 300.

12 Q. Or \$300 an hour?

13 A. Three hundred ten, 12, depending on
14 where I'm at.

15 Q. But for -- for the purposes of being
16 an expert witness in this case, you decided that you
17 could charge \$430 an hour?

18 A. Correct.

19 Q. And you're being paid at that rate?

20 A. That is correct.

21 Q. Okay. We'll get into -- I want to
22 clean up the payments and all.

23 A. Sure.

24 Q. We'll probably do that at the end.

25 Okay. So now -- now we know what you did. You

1 looked at documents two days before your deposition
2 was originally scheduled in 2011. It was then
3 continued to eventually today, right?

4 A. Yes.

5 Q. But -- but the only time that you did
6 any additional work was what you've just described;
7 is that right?

8 A. That is correct.

9 Q. The two days before that deposition
10 was scheduled?

11 A. Yes.

12 Q. It was canceled?

13 A. Correct.

14 Q. And continued?

15 A. Correct.

16 Q. Okay. But you've done nothing since
17 then?

18 A. Since that time, yes, I did.

19 Q. Oh, okay. What -- what -- and what
20 have you done?

21 A. I spent approximately eight hours now
22 reviewing the documents that I had made copies of
23 and re-reviewing all of the referenced documents
24 that were in the -- referenced in the -- the expert
25 report.

1 Q. Was that in that two days before your
2 deposition was originally scheduled?

3 A. The second time. This is two days
4 before -- let's say three days ago, in essence,
5 three days ago.

6 Q. Okay. Okay. So there was the initial
7 re-review of Mylan documents?

8 A. Yes.

9 Q. Two days before your 2011 deposition
10 was to be taken?

11 A. There was a two hour review, yes.

12 Q. Okay. Two hour review after a day and
13 a half spent finding and printing documents,
14 correct?

15 A. Yes.

16 Q. And then three days ago?

17 A. Yes.

18 Q. You spent another eight hours
19 reviewing these documents?

20 A. That is correct.

21 Q. The same documents?

22 A. The same documents and the ones that
23 are in here that we -- you wanted to go through.

24 Q. When you say the same documents and
25 the ones that are in here, that leads me to believe

1 that the documents you just reviewed three days ago
2 are not the same documents that you reviewed before
3 your deposition was to be originally taken earlier
4 in 2011. Am I right?

5 A. I don't recall, because some of the
6 documents I looked at electronically. In this case,
7 I ended up printing anything that had anything to do
8 with the wording in my deposition because I wanted
9 to make sure -- sir, the way that unfortunately the
10 copies were made, there were many, many Mylan
11 documents which didn't have M numbers on them, they
12 had another number. So -- and so in my report,
13 there are Mylan documents referred ATA or ATV, or
14 they could be plaintiff 1, 2, 3,4. And I had no way
15 without -- I mean, each one took 45 minutes to
16 figure out which was the right copy, therefore, I
17 made copies of anything that was related to it,
18 which appears in here. This is 100 percent. Or
19 there could be something in there (indicating). But
20 these were more, I would say pertinent. Then I had
21 to read these in order to see if they were the right
22 P documents or ATA documents. So I had a process.

23 Q. I got you. I understand. In addition
24 to reviewing the documents contained in the notebook
25 in front of you, have you done anything else in

1 preparation for this deposition?

2 A. No.

3 Q. Have you talked to Ms. Carter or any
4 of the Plaintiff's lawyers?

5 A. Nobody, no human being, not even my
6 wife.

7 Q. Well -- all right. So you haven't had
8 any conversations with any of the Plaintiff's
9 lawyers about anything related to preparation for
10 this deposition today?

11 A. No. Yesterday, I met with Meghan for
12 a period of approximately four hours of which we
13 probably spent a half hour talking and I spent three
14 and a half hours or so trying to, again, mentally
15 organize myself.

16 Q. You met with -- with Ms. Carter
17 yesterday for four hours?

18 A. Yes.

19 Q. In preparation for your deposition?

20 A. Correct. We met for about a half
21 hour --

22 Q. What did she tell you?

23 A. She gave me -- she said it's, you
24 know, expect the same type of questions. Expect
25 that since Harvey didn't have an opportunity --

1 yourself, Mr. Kaplan.

2 Q. Harvey is fine.

3 A. Didn't have an opportunity -- okay.

4 Didn't have an opportunity to ask you questions, he

5 will ask questions about Mylan. And you just want

6 to make sure you are familiar with the documents.

7 That was the extent of our conversation.

8 Q. Well, did you have any specific

9 discussions about any specific issues related to

10 Mylan?

11 A. Zero.

12 Q. Zero?

13 A. Zero. Absolutely zero.

14 Q. So what did you do for the three and a
15 half, four hours?

16 A. We talked a lot about different stuff.

17 Q. But that's at \$430 an hour.

18 A. Sir, you're talking about two

19 different things. \$430 an hour is my rate. What I

20 bill is not my total hours put into a project.

21 Never, ever, have I ever billed at what actually

22 I've put in. I have always billed less than, not

23 even equal to it, just because I feel my efficiency

24 may not be 100 percent. I should be billing when my

25 efficiency is 100 percent.

1 Q. Were you efficient yesterday?

2 A. Was I fishing?

3 Q. Were you efficient?

4 A. Was I efficient yesterday, no, not
5 particularly.

6 Q. You weren't?

7 A. No.

8 Q. So for the four hours that you spent
9 with Meghan yesterday, how much are you going to
10 bill for?

11 A. I haven't decided.

12 Q. Okay. So you could bill up to four
13 hours at \$430 an hour?

14 A. Oh, no. I could bill up to my travel
15 time, an hour and a half to get there, an hour and a
16 half to get back. I could -- I could -- I'll have
17 to look back, see what I accomplished, and determine
18 whether or not I bill for eight hours.

19 Q. Oh, okay. So you may bill for eight
20 hours?

21 A. That is a possibility.

22 Q. Yesterday?

23 A. Yes.

24 Q. Okay. Because you came over here to
25 Manhattan?

1 A. Correct. It takes about two hours
2 door to door to get here and about two hours to get
3 back.

4 Q. Okay. Did you discuss any of your
5 opinions as to Mylan with Meghan yesterday?

6 A. No, none at all.

7 Q. Did you review these documents with
8 Meghan?

9 A. No. The only -- she didn't look at
10 the documents but I explained to her that --

11 Q. When I say Meghan, I'm sorry. We're
12 being a little informal.

13 A. Yeah. I understand.

14 Q. We're all on kind of a first name
15 basis.

16 A. I explained to her that I had gone
17 back to the Internet to see if there were any
18 references in warning letters or the like concerning
19 quality agreements or audits to see if specifically
20 the FDA issued warning letters that clearly outlined
21 or inferred that quality agreements and quality
22 audits were quite specifically a GMP requirement.

23 Q. And did you find any?

24 A. Yes, I did.

25 Q. You did? And are those --

1 A. They are not here, but I'll show you
2 them in a minute, if you'd like.

3 Q. You're saying that you found documents
4 from the FDA saying what now?

5 A. That there was a warning letter on a
6 company associated with not having quality
7 agreements and/or not performing audits.

8 Q. Was that on Mylan?

9 A. No. That's on other industry
10 companies, drug companies.

11 Q. What was the context of the FDA
12 document that you're talking about that --

13 A. Would you like me to show you?

14 Q. Well, just first answer my question.

15 A. Surely.

16 Q. Okay. Give me the context. You said
17 you found an FDA document or documents regarding a
18 warning letter issued to a company for not having a
19 quality agreement or -- or not performing?

20 A. Audits. G&P audits.

21 Q. Okay. Give me the context of that.
22 When, was the company?

23 A. I would have to pull the document to
24 do that.

25 Q. What's your best recollection?

1 A. I would like to pull the document.

2 Q. Let me just ask you, what's your best
3 recollection right now?

4 A. My best recollection is I was looking
5 at drug companies that were inspected that received
6 warning letters. There were three or four that I
7 saw on the screen, I printed two of them.

8 Q. But -- but the drug company -- let me
9 just ask you this: So you're saying you pulled
10 something from the Internet?

11 A. Yes.

12 Q. Warning -- there were two warning
13 letters that you found?

14 A. Correct.

15 Q. From the FDA to a manufacturer?

16 A. To a manufacturer, correct, and a
17 contracting company.

18 Q. What's a "contracting company"?

19 A. A company who is the sponsor.

20 Q. When you say "the sponsor," what do
21 you mean by "the sponsor"?

22 A. One company sells the product with
23 their name on it, the other company makes it for
24 them.

25 Q. When you say "the sponsor," who is the

1 sponsor?

2 A. It would be the company that sold the
3 product.

4 Q. What are they sponsoring?

5 A. It's just a term that is sometimes
6 used. It's the manufacturer -- it's the name that's
7 on the label.

8 Q. The name that's on the label of what?

9 A. Of the product.

10 Q. Is that the holder of the NDA?

11 A. I don't know.

12 Q. What -- what do you call the holder of
13 an NDA or an ANDA?

14 A. I don't know what the official term
15 is. The holder of the NDA.

16 Q. You don't know?

17 A. I don't know what the formal term is.

18 Q. In all of the years that you were with
19 Johnson & Johnson in the drug industry, you don't
20 know what you call the company that holds the NDA?

21 A. We'd say it owns the NDA.

22 Q. What?

23 A. The company that owns the NDA. It's
24 what I would call it, perhaps it's an informal term.

25 Q. And you don't know what you call the

1 company that owns or holds the ANDA?

2 A. No.

3 Q. What is an ANDA?

4 A. Abbreviated new drug application.

5 Q. What is the difference between an ANDA
6 and an NDA?

7 A. Sir, you're going beyond my expertise,
8 you're going into regulatory affairs areas.

9 Q. All you have to say is I don't know.

10 A. I don't know.

11 Q. Okay. Is that your answer?

12 A. I don't have an expert opinion on
13 that. I don't know.

14 Q. Okay. But I just want your honest
15 answer. If you don't know, just say you don't know.

16 A. I don't know.

17 Q. And you told me before, you said the
18 term sponsor means the company that sold the product
19 and the contracting company is --

20 A. The company that manufactured the
21 product. The contractor or contracting company.

22 Q. As -- as to DIGITEK, who is the holder
23 of the ANDA?

24 A. I believe it's Actavis from the
25 records that I read.

1 Q. And who is the manufacturer DIGITEK?

2 A. The manufacturer is Actavis.

3 Q. What is the significance of Actavis
4 being the holder of the ANDA as to GMP compliance?

5 A. Well, they need to, as all companies
6 do, need to comply with GMP. I don't know how I
7 could be more specific.

8 Q. Okay. It's your understanding that
9 Mylan is not the manufacturer of DIGITEK?

10 A. Mylan doesn't manufacture that
11 product.

12 Q. Mylan --

13 A. I'm not using that as a formal term.
14 I am saying that they do not manufacture that
15 product.

16 Q. They also -- Mylan is not the holder
17 of the ANDA?

18 A. That is my understanding, correct.

19 THE VIDEOGRAPHER: We're off the
20 record at 10:15.

21 (Recess taken.)

22 THE VIDEOGRAPHER: We are back on the
23 record. The time is 10:19.

24 BY MR. KAPLAN:

25 Q. When I was asking you questions about

1 the difference between NDA and ANDA and you said I
2 don't know, that's going beyond my area of
3 expertise.

4 A. Correct.

5 Q. You are not an expert in regulatory
6 affairs?

7 A. That is correct.

8 Q. FDA regulatory affairs?

9 A. That is absolutely correct.

10 Q. You don't hold yourself out to be an
11 expert?

12 A. That's correct.

13 Q. All right. Can you define -- you used
14 the term contract manufacturer?

15 A. Yes.

16 Q. What is a contract manufacturer?

17 A. It's -- it's a company that you have a
18 formal agreement with that manufactures product
19 to -- to some predetermined specification.

20 Q. Well, in -- in this case, you told me
21 that Actavis is the manufacturer of DIGITEK?

22 A. Correct.

23 Q. Actavis is the holder of the ANDA?

24 A. That's what I read.

25 Q. So Actavis manufactures DIGITEK in

1 accordance with the specifications set forth in the
2 ANDA; is that right?

3 A. I don't know. I haven't read the
4 ANDA.

5 Q. So your -- that is something that
6 you're just not familiar with?

7 A. It's something I wouldn't read because
8 it not within my expertise.

9 Q. Okay. Well, I'm just trying to set
10 some basic understandings here --

11 A. Yes.

12 Q. -- or lack thereof.

13 A. Yeah.

14 Q. I mean, maybe -- maybe you don't
15 understand the -- the roles of the various companies
16 involved here.

17 A. Uh-huh.

18 Q. But I want to find out what you know
19 and what you don't know. So you don't know whether
20 Actavis as the holder of the ANDA for DIGITEK was
21 charged with the responsibility for manufacturing
22 DIGITEK in accordance with the specifications set
23 forth in the ANDA?

24 A. Sir, you're going to have to repeat
25 that. I'm sorry.

1 MR. KAPLAN: Would you repeat that?

2 (Record read.)

3 MS. CARTER: Object to form.

4 A. If I understand the question, you're
5 asking there is an ANDA. And in that, it has
6 content that talks about the CMC section. It talks
7 about chemistry, manufacturing, and control. I as
8 part of my profession, I don't go into either an NDA
9 or an ANDA and look what the agreement has been
10 reached between -- between the company and the FDA.
11 So I don't -- I don't read that at all. I have no
12 interest in it whatsoever.

13 BY MR. KAPLAN:

14 Q. How does the FDA qualify a
15 manufacturer?

16 A. How do they qualify a manufacturer?
17 They do a preapproval. They -- they read whatever
18 the submission is, whether it's medical device with
19 PMA or 510K or an ANDA or an NDA. They then
20 schedule, in most instances, a preapproval
21 inspection. They would come in and they would
22 review your GMP, they would spend whatever time they
23 felt was appropriate, and then they would issue you
24 as -- as a part of that approval process, issue you
25 an approval letter.

1 Q. In this case, in this situation with
2 regard to DIGITEK, Actavis was qualified by the FDA
3 as the manufacturer of that product, right?

4 A. I -- I don't know. I didn't see that
5 document. It was done apparently in the '90s
6 sometime.

7 Q. Who do you think was qualified as the
8 manufacturer of DIGITEK?

9 A. I don't know.

10 Q. You have no idea?

11 A. No, I didn't see the documents.

12 Q. Do you think it was Mylan?

13 A. I have no idea.

14 Q. Come on. You know that Mylan was not
15 the manufacturer, right?

16 A. I know they did not manufacture the
17 product.

18 Q. You know that Actavis did?

19 A. Correct.

20 Q. Is it fair to assume that if Actavis
21 was manufacturing DIGITEK, they were qualified to do
22 so by the FDA?

23 A. I would say it's fair to assume that
24 whatever FDA procedures were in place at the time of
25 approval that those procedures were followed.

1 Q. By Actavis?

2 A. By the FDA in conjunction with
3 Actavis.

4 Q. But not Mylan?

5 A. But not Mylan? I don't know what
6 Mylan's role would be.

7 Q. Well, you -- you told me it was your
8 understanding that Mylan sold DIGITEK, right?

9 A. Correct.

10 Q. How is it that Mylan sold DIGITEK?

11 A. Some type of agreement, verbal or
12 written agreement, would have to be reached, and
13 then they would sell the product. And I suppose
14 there is -- there is some licenses that have to be
15 obtained from the FDA, licenses which I'm not
16 familiar with.

17 Q. Well, tell me in this situation what
18 you have seen that tells you how it is that DIGITEK
19 came to be sold by Mylan.

20 A. I -- I didn't go back that far in
21 terms of reviewing that documentation.

22 Q. What documentation are you talking
23 about?

24 A. I -- I didn't look at anything prior
25 to '99, let's say.

1 Q. So in all of your review of -- of --
2 of documents in preparation for rendering your
3 opinions which are contained in your report of
4 June 15, 2010, and in preparation for your
5 deposition on June 29 and again -- of 2010, and
6 again today, February 16, 2011, you -- you reviewed
7 no document that gave you any understanding of the
8 relationship between Actavis and Mylan?

9 A. No formal document that -- that's
10 correct, no formal document. It would have been
11 implied or stated to some extent in memos and the
12 like.

13 Q. But I'm going to ask the court
14 reporter to repeat the question again, and I am
15 going to ask you to answer it, please.

16 A. Sure.

17 Q. Yes or no. Yes, you did review any
18 document or no, you didn't review?

19 MR. KAPLAN: Would you repeat that?

20 (Record read.)

21 A. I read documents, yes, that did
22 have -- gave me an understanding of the
23 relationship.

24 Q. I'm going to ask you what your
25 understanding is of the relationship and what

1 documents you read to --

2 A. Well, I don't recall the documents
3 that I read, so that's not going to be possible.
4 And my understanding is that Mylan had some -- an
5 agreement with Actavis that they would be selling
6 the product and that Actavis would be manufacturing
7 that product.

8 Q. Is that document that you were just
9 talking about contained in the binder in front of
10 you?

11 A. Sir, I don't know what document it is,
12 where I -- or I would have made that determination.

13 Q. Who had the authority to confer upon
14 Mylan the right and responsibility of manufacturing
15 DIGITEK?

16 A. You have to repeat that, sir.

17 (Record read.)

18 A. I don't know who had the right. I'm
19 not -- I'm not sure I actually understand the
20 question.

21 Q. What don't you understand?

22 A. I don't understand the question.
23 Could you rephrase it, please.

24 Q. Okay. Is it your understanding that
25 it is the FDA and only the FDA that would have the

1 authority to confer upon Mylan the right to
2 manufacture DIGITEK?

3 A. I don't know the process with Mylan
4 that would give them the authority to be able to
5 sell it. I was not involved with the regulatory
6 affairs negotiations between the seller or the
7 distributor of the product and the FDA.

8 Q. That was not my question, and I'll ask
9 the court reporter to read it back again. And
10 concentrate on this, take your time.

11 A. Yeah.

12 MR. KAPLAN: Please read back the
13 question.

14 (Record read.)

15 A. Oh, on Actavis? Oh, yes.

16 Q. It's the FDA?

17 A. That's correct.

18 Q. Only the FDA?

19 A. As far as I know -- well, I'm only
20 involved with the FDA, but I know it is the FDA.
21 Whether there are other legal groups, I don't know.

22 Q. Mylan has no authority to authorize
23 Actavis to manufacture DIGITEK?

24 A. They don't have what?

25 Q. Mylan has no authority to authorize

1 Actavis to manufacture DIGITEK?

2 A. Using the word "authorize," I believe
3 that's correct.

4 Q. Is there some other word that you
5 would use?

6 A. I don't know. Well, they would --
7 they would establish an agreement, and as part of
8 the agreement, to uphold the agreement, they would
9 manufacture certain number of lots, certain
10 quantity, under certain specifications, and other
11 conditions, for Mylan. That I believe is the
12 relationship that which I'm involved with in my --
13 in my trade.

14 Q. I don't know what you mean. Can you
15 explain that, the relationship you're involved with
16 in your trade?

17 A. I'm involved -- the expertise that I
18 bring is good manufacturing practices. Once an
19 agreement is reached, a verbal agreement is reached
20 between the two parties, I would look at the
21 relationships of the supply and determine whether
22 between the two parties my company, which would be
23 the equivalent of Mylan, and the contract
24 manufacturer, and I would determine whether or not
25 the GMP conditions are adequately defined and

1 whether adequately executed.

2 Q. Have you seen any such agreement?

3 A. I have not seen a -- I saw a draft of
4 a quality agreement which was not approved.

5 Q. You have seen no other agreement
6 between Actavis and Mylan?

7 A. There was a supply agreement. I have
8 not read the supply agreement.

9 Q. Why not?

10 A. Well, I didn't see it in the records.

11 Q. Did you ask for it?

12 A. I did not ask for it.

13 Q. So in all of the work you've done, all
14 hours that you've billed, all of the time that
15 you've spent preparing for your report and writing
16 your report and giving your deposition, preparing
17 for your deposition, both on June 29, 2010 and again
18 today on February 16, 2011, you've never asked for
19 any supply agreement between Mylan and Actavis,
20 correct?

21 A. I don't recall asking specifically for
22 a supply agreement.

23 Q. So the answer to my question is no, I
24 have not?

25 A. No, I have not.

1 Q. And you referred to Actavis as a
2 contract manufacturer, that's -- that's a term of
3 art. What does that mean?

4 A. It means a company that's making
5 product for you, making -- manufacturing product for
6 you.

7 Q. And your understanding then is that --
8 that Actavis was a contract manufacturer?

9 A. That's a term that is used in the
10 industry, yes.

11 Q. What -- is that pursuant to
12 regulation, contract manufacturer?

13 A. Well, the FDA does use that term in
14 some of its documents, so I would say it's an
15 industry -- external manufacturer or contract
16 manufacturer are the most common terms.

17 Q. Is there a difference between a
18 manufacturer that is the holder of an ANDA and a
19 contract manufacturer?

20 A. It's -- I -- from what I would say the
21 Mylan standpoint based upon my experience as a Mylan
22 perspective, there is no difference.

23 Q. That wasn't my question.

24 A. In terms of GMP.

25 Q. That wasn't my question.

1 A. Okay.

2 Q. I'm going to ask the court reporter to
3 read back my question and see if you can try to
4 answer specifically what I asked you.

5 (Record read.)

6 A. I am not aware of any difference from
7 a Mylan perspective, from a GMP perspective.

8 Q. Could you be more specific?

9 A. That the GMP is all of the controls
10 that are necessary -- if I'm the seller of a
11 product, I am -- if I'm a distributor of a product,
12 I sell it, I market it. I have a responsibility to
13 all of those involved with it, the customers, the
14 patients, et cetera. I have a responsibility -- and
15 to the FDA, to make sure that GMPs are upheld both
16 by my company and by the company manufacturing. So
17 that the same level of controls in terms of GMP are
18 in effect between the two parties, that they
19 compliment one another to meet the GMP requirements.

20 Q. So are you saying that according to
21 the code of federal regulations which the GMPs are
22 contained?

23 A. Correct.

24 Q. That Mylan as the seller of DIGITEK
25 had responsibility under the law to make sure that

1 GMPs were upheld in the manufacture of DIGITEK?

2 A. That is correct.

3 Q. And can you -- can you cite me to
4 that -- to that -- those regulations that put that
5 responsibility on a seller?

6 A. I cannot right this second.

7 Q. Well, take your time.

8 A. Well, I don't have it here, but I
9 believe there is. I cannot cite it currently, but I
10 believe there's enough information in print that
11 says that if I am Mylan, I am responsible for
12 ensuring that product manufactured in my name for me
13 has to meet GMP requirements.

14 Q. Okay. And I'm just asking you to tell
15 me, show me what it is that you have reviewed, seen,
16 relied upon in arriving at your opinions in this
17 case that leads you to believe that a seller of a
18 product has the responsibility to make sure that the
19 manufacturer of the product who is the ANDA holder
20 complies with GMPs?

21 A. I can tell you through my experience
22 that I've been trained to -- to -- to ensure -- to
23 establish a relationship with the contract
24 manufacturer and that ensuring that I as -- Mylan,
25 if you will -- and the contractor have a full

1 compliment and meet the GMP requirements that I am
2 responsible and accountable for them.

3 Q. I'm going to move to strike that as
4 nonresponsive and ask the court reporter to read
5 back my question. And ask you to answer the
6 question that I asked you.

7 A. Okay.

8 (Record read.)

9 A. I cannot show you right this second
10 what it is. It's just that is my understanding
11 based upon years of experience and reading documents
12 and warning letters and GMPs and preambles and
13 guidance documents, I would say that is my
14 understanding. So I cannot -- if you want to
15 restate the question.

16 Q. You cannot?

17 A. I don't know. Restate the question.
18 I want to make sure I answer it.

19 Q. There is no document --

20 A. That I can point to.

21 Q. That you can point to. There is no
22 document upon which you rely to conclude that Mylan
23 as the seller of DIGITEK had the responsibility for
24 ensuring that Actavis as the ANDA holder and
25 manufacturer of DIGITEK complied with GMPs?

1 A. I cannot point to a document.

2 Q. You can't point to a document in
3 your -- referenced in your report, can you?

4 A. That is correct.

5 Q. You can't point to a document, any
6 document that you brought here today, can you?

7 A. I -- I don't know. I'd have to -- at
8 this particular point, I can't point to a document.
9 I'd have to think about it and do a little more
10 research in order to confirm what I know.

11 Q. With all due respect, I asked you if
12 you came here today prepared to give your opinions
13 and you said yes.

14 A. I was prepared.

15 Q. You are prepared, aren't you.

16 A. I am prepared. But you're asking me a
17 question that I cannot answer at this particular
18 point.

19 Q. Pretty fundamental to your opinions as
20 to Mylan, isn't it?

21 A. If that's -- I would not say that, no.
22 I don't think it's fundamental to our discussions.

23 Q. You don't think that the legal
24 requirements for ensuring compliance with GMPs is
25 fundamental to your opinions as to Mylan?

1 A. I am saying that I am aware of what
2 are industry norms, what are standards, between a
3 contracting company and a contract manufacturer, but
4 I cannot pinpoint a document right this second which
5 establishes that in terms of law.

6 Q. The legal responsibility for complying
7 with GMPs is fundamental to any opinion you are
8 offering in this case, isn't it?

9 MS. CARTER: Object to form.

10 A. Yes.

11 BY MR. KAPLAN:

12 Q. And you keep referring to Actavis as a
13 contract manufacturer.

14 A. The relationship that Mylan has, if
15 I'm looking at it from Mylan's perspective, they are
16 what's referred to as a contract manufacturer. And
17 Mylan refers to them as a contract manufacturer.

18 Q. What's the basis for concluding that
19 Actavis is a "contract manufacturer"?

20 A. It's in various documents where they
21 talk -- talk to Actavis as the contract
22 manufacturer.

23 Q. How does a contract manufacturer
24 differ from a manufacturer who has an approved ANDA
25 approved by the FDA? What is the difference?

1 A. I don't see any difference. From
2 Mylan's perspective.

3 Q. Well, from your perspective?

4 A. But my perspective is in terms of my
5 experience, I've never been a contract manufacturer.
6 My perspective is as the company that distributes
7 the product that I am obligated, I've been trained
8 to assume that obligation that I have to be in
9 compliance with GMP, and that the company that makes
10 the product for us has to be compliant to GMP.

11 Q. When you say I have to be compliant
12 with GMP, what do you mean?

13 A. I means -- some people refer to the
14 distributor as a virtual company. As part of a
15 virtual company, you'll have systems and procedures,
16 you'll have specifications that you approve. You
17 will have other procedures that are approved. You
18 perhaps have complete handling responsibility. And
19 those would be -- there are supposed to be
20 established between you and the contractor as to
21 what my obligations were to compliment the FDA's
22 requirements and what your obligations are to meet
23 FDA requirements.

24 Q. You started by saying some people
25 refer to a distributor as a virtual company. When

1 you say "some people," who are you talking about?

2 A. In the industry, it's a common term.

3 Q. Who is the industry?

4 A. The industry are my peers.

5 Q. I don't know who your peers are.

6 A. My peers are companies that I have
7 either worked for or have some relationship with.
8 It's -- I would call it it's an informal term that
9 is used.

10 Q. Is the FDA --

11 A. No, the FDA does not use that term,
12 that I've ever seen.

13 Q. So the FDA that has established good
14 manufacturing practice regulations does not use the
15 term "virtual company"?

16 A. As far as I know. I don't know if
17 they use that term. I've never seen it used by
18 them.

19 Q. And you said that a seller of a
20 product has to approve specifications --

21 A. That's correct.

22 Q. -- for a product? Can you -- can you
23 cite me to the -- to the regulations that impose
24 that responsibility on the seller?

25 A. Sir, if I -- I cannot cite you to the

1 regulation.

2 Q. But it's your understanding that the
3 FDA requires a seller of a product, in this case
4 Mylan, to approve manufacturing specifications for
5 the manufacture of DIGITEK by Actavis?

6 A. To approve product specifications.

7 Q. What's the difference between
8 manufacturing specifications and product
9 specifications?

10 A. Product specifications are an end
11 specification. Manufacturing is how you make it.

12 Q. Be a little more specific.

13 A. Manufacturing would be the process of
14 putting two chemicals together to -- and et cetera,
15 to process it to become a finished product. And at
16 that particular point, as a finished product, you
17 would have a product specification.

18 Q. You're saying that the responsibility
19 for the product specifications with regard to
20 DIGITEK rests with Mylan?

21 A. A portion of that, most certainly.

22 Q. What portion?

23 A. They need to have approved
24 specifications in their system as to what they are
25 buying. You have to know what you're buying. What

1 am I buying? I define it as a specification of
2 which Mylan or -- sorry -- Actavis, in this case, or
3 the contractor, would manufacture in accordance to.
4 So they deliver a product that meets my
5 specification. I take ownership for it because it's
6 my product, it is my specification.

7 Q. So it's your understanding that --
8 that Mylan tells Actavis what the specifications for
9 DIGITEK are to be?

10 A. No, I didn't say that. I said that I
11 don't know who tells who. All I can tell you is
12 that Mylan would have an approved specification that
13 they would use to determine whether or not the
14 product met their own specification and was fit to
15 be distributed.

16 Q. Let's go back. Isn't it the FDA that
17 has to approve the specifications for the
18 manufacturer of DIGITEK?

19 A. No.

20 Q. No?

21 A. Not the specifications. They would --
22 I wouldn't use that term. You asked me
23 specifications, I would say no.

24 Q. So it's not the FDA that has to
25 approve the specifications for the manufacture of

1 DIGITEK?

2 A. The FDA does approve certain
3 information that's required by -- by them. That is
4 contained in an ANDA and an NDA, and the product has
5 to be manufactured according to those requirements.

6 Q. Well, what -- what authority does
7 Mylan have with regard to product specifications?

8 A. I don't know. If I understand your
9 question, I would say -- could you repeat the
10 question? I don't think I'm answering the right
11 question.

12 (Record read.)

13 A. Mylan has an obligation to have
14 product specifications that they use to determine
15 the acceptability of a product to be distributed in
16 their name.

17 Q. I'm going ask you the question again.
18 I'll just repeat it. What authority does Mylan have
19 under the law with respect to product specifications
20 for DIGITEK?

21 A. I don't know. Under the law.

22 Q. Well, we were going through the
23 notebook you brought of all of the Mylan documents
24 that you have looked at since your deposition was
25 taken initially on June 29, 2010?

1 A. Right.

2 Q. We've actually only gotten through two
3 documents. There was an exhibit M55 and an exhibit
4 M53. Tell me what the next document is.

5 So the next document you're handing me is
6 marked Exhibit M21, and it is a e-mail from a John
7 Deiriggi, D-E-I-R-I-G-G-I, to Hal Korman,
8 K-O-R-M-A-N, dated January 4, 2007. And then an
9 e-mail below that from Walt Owens to John Deiriggi
10 dated January 4, 2007. There's nothing that you've
11 highlighted here.

12 A. There was nothing of interest in
13 there.

14 Q. All right. So M21, nothing of
15 interest, right?

16 A. Correct.

17 Q. The next Mylan document that you
18 reviewed.

19 A. Here's another one.

20 Q. Okay. The next document you've handed
21 me is another exhibit from a previous deposition,
22 and it's marked Exhibit M25. It's an e-mail from
23 Chuck Koons to Hal Korman dated April 27, 2008. And
24 you have highlighted a portion on the first and
25 second page, I'll just refresh your recollection.

1 The portion you've highlighted starts with
2 "Actavis's U.S. head of quality would be calling."
3 Then, "Mike Adams and I spoke to her on the phone,
4 and she described that the PAI had been going on for
5 six weeks and that they were being "beaten up" by
6 FDA. She stated that the reason the recall was
7 expanded to all DIGITEK was that FDA felt that there
8 weren't adequate controls on their tablet presses to
9 ensure that the double tablet issue couldn't have
10 happened previously." Then you -- then you
11 highlighted a portion of a sentence that says that
12 "other products were being recalled."

13 And then on the second page of M25,
14 you've highlighted "FDA is focusing on Amide's
15 systems to control and ensure product quality rather
16 than simply having concerns over just one
17 investigation." And then finally, you highlighted
18 the following: "Mike Adam, Cass, C-A-S-S, Bird, and
19 Ann Wolf, who've lead the charge from the MPI side."

20 So tell me what you learned or what was
21 the significance there.

22 A. Well, there is only one sentence, if
23 you will, that I would say is -- was meaningful for
24 me. And she stated -- it says, "she stated the
25 reason the recall was expanded to all DIGITEK was

1 that FDA felt there weren't adequate controls on
2 their tablets -- tablet press, to ensure that double
3 thick issues couldn't have happened previously."
4 That was the -- to me the notable sentence.

5 Q. Okay. And by the way, these documents
6 that you've just gone through, you hadn't reviewed
7 those prior to rendering your opinions in this case?

8 A. No, I -- I almost assuredly did see
9 them. M25, I did.

10 Q. Okay. And if they were significant to
11 you, you would have referenced them in your report?

12 A. If they were significant -- if I felt
13 they were significant at the time, I would have
14 referenced them in my report.

15 Q. Because all of your opinions are
16 contained within the four corners of your report?

17 A. That is correct. That is correct.

18 Q. And you understand that that is your
19 obligation here?

20 A. You've asked me that and I will repeat
21 it and say I understand that.

22 Q. I just want to make sure we're on the
23 same wave length.

24 A. We're on the same wave length
25 100 percent.

1 Q. Thanks. And reference was made to
2 Amide, A-M-I-D-E. You understand that when
3 reference was made to Amide, that's Actavis?

4 A. That is correct. That's my
5 understanding.

6 Q. Okay. And you also understand that
7 throughout the documents, when reference is made to
8 Bertek, B-E-R-T-E-K, that means Mylan?

9 A. That's correct. That's my
10 understanding.

11 Q. All right. The next document that you
12 reviewed since your deposition was taken initially
13 on June 29, 2010.

14 A. Reviewed or rereviewed?

15 Q. You can tell me whether you reviewed
16 or rereviewed.

17 A. Well, I reread. I reread Adams.
18 There was nothing --

19 Q. You reread what?

20 A. I'm sorry. Let me tell you what I
21 reread. The deposition taken on Michael Adams
22 January 22, 2010, I think that's it. And I reread
23 it to just familiarize myself. They are long
24 documents, hundreds of pages.

25 Q. When you say you reread the deposition

1 of Mike Adams, don't you recall that at your
2 previous deposition when you were asked whether you
3 reviewed any Mylan depositions, you said the only
4 one you looked at was Chuck Koons?

5 A. I -- I read documents where I quickly
6 went through them, and perhaps I was in error. I
7 think I did read Michael Adams because I did see
8 certain phrases where -- they were interesting
9 phrases. They were at least mentally notable to me.

10 Q. So you think that when you -- when you
11 testified on June 29, 2010 that the only Mylan
12 deposition you reviewed was Chuck Koons, you were
13 wrong?

14 A. I believe I was wrong, correct.

15 Q. And you think you also had reviewed
16 Mike Adams' deposition?

17 A. I'm sorry, I think I got these
18 backwards. Could you repeat your question?

19 Q. You think that before your June 29
20 deposition was taken, you had also reviewed Mike
21 Adams' deposition?

22 A. I believe I did, yes.

23 Q. And then you re-reviewed Mike Adams'
24 deposition?

25 A. Correct.

1 Q. After June 29, 2010?

2 A. That is correct.

3 Q. And what did you learn from that?

4 A. Nothing.

5 Q. Did you look at any other Mylan
6 deposition?

7 A. I looked at Chuck Koons.

8 Q. Again?

9 A. Yes.

10 Q. What did you learn from that?

11 A. I learned that Mr. Koons had not a
12 good memory.

13 Q. Well, I'm going to move to strike that
14 as nonresponsive.

15 A. Nothing that I recall notable.

16 Q. How is your memory?

17 A. Mediocre to good. Depends. Sometimes
18 it's very, very good.

19 Q. How is it today?

20 A. I believe it's pretty good.

21 Q. Okay. All right. Any other Mylan
22 depositions that you reviewed?

23 A. No, that's it. If it's here, then I
24 reviewed it.

25 Q. So Mike Adams and Chuck Koons, and

1 there's nothing remarkable that you gleaned from
2 either of those depositions?

3 A. No.

4 Q. All right. What is the next document
5 that you reviewed? Since June 29, 2010?

6 A. I could short -- well, I'll go through
7 it per your process.

8 Q. If you want to shortcut it, I'm all in
9 favor of it. Tell me how you can shortcut it.

10 A. Well, let's go through it so I don't
11 misspeak.

12 Q. I don't want you to misspeak.

13 A. Okay. I read this particular
14 document, you can look at it. And I made no --
15 there was nothing remarkable in there.

16 Q. Okay. So what you're handing me is a
17 document marked Exhibit M65, which bears a Bates
18 stamp -- which bears Bates stamp numbers UD as in
19 dog, LL 000005805 through 5818.

20 (Cell phone interruption.)

21 Q. Does your handwriting appear anywhere
22 on here?

23 A. Yes.

24 Q. Is it on the front page?

25 A. Yes, it is.

1 Q. And if I can read this correctly, it
2 says receiving and then there's an arrow, four of
3 96, 00S thickness found at UDL PKG 70175A. What
4 does that mean?

5 A. It's -- it's just when I looked
6 through it, there was an out of specification when I
7 review documents as any GMP person does, he or she
8 would look for the term out of specification,
9 because it's potentially notable when I reviewed it.
10 It was meaningless in the context to my expert
11 opinion.

12 Q. Who is UDL?

13 A. UDL is apparently a contract packaging
14 firm that I believe there's probably a Mylan
15 relationship with.

16 Q. What do they do?

17 A. They -- I think they form blister
18 packs, at least I read that.

19 Q. Blister packs of?

20 A. Of I would guess Digoxin, and perhaps
21 others, I don't know, but it was not important to
22 me. Okay?

23 Q. So there is nothing important to you
24 about document M65 that has anything to do with any
25 opinion that you're rendering in this case?

1 A. Not in the least bit.

2 Q. Okay. Thank you. Okay. The next
3 Mylan document that you reviewed.

4 Okay. You've handed me a document that
5 is Exhibit M52 which bears the Bates stamp numbers
6 UDLL 0000014256 through 14268. UDL document you've
7 highlighted that it's from Lee Radtke dated
8 February 10, 2007, re 483/warning letter summary for
9 Actavis (Amide.) And I see no other highlights
10 throughout the document.

11 A. It was not remarkable.

12 Q. There was nothing remarkable about
13 Exhibit M52.

14 A. Correct.

15 Q. It had no bearing on your opinion in
16 any way, shape, or form; is that right?

17 A. Zero. That is correct.

18 Q. Zero, zero, zippo. It's 11 o'clock.
19 You want to take a break?

20 A. No.

21 Q. You don't? I do.

22 THE VIDEOGRAPHER: We're off the
23 record. The time is 11:02. This is the end
24 of tape 1.

25 (Recess taken).

1 (Whereupon, Rick Fern joined the
2 deposition.)

3 THE VIDEOGRAPHER: We're back on the
4 record. The time is 11:18. This is the
5 beginning of tape two.

6 BY MR. KAPLAN:

7 Q. Okay. Mr. Kenny, I think we had just
8 talked about Exhibit M65, which you told me was one
9 of the Mylan documents that you reviewed since your
10 deposition was taken on June 29, 2010, and that
11 there was nothing remarkable about that document,
12 correct?

13 A. That is correct.

14 Q. All right. Moving on. Let's go to
15 the next Mylan document in your notebook, please.

16 A. (Handing).

17 Q. You're handing me a document which was
18 previously marked as deposition Exhibit M47 bearing
19 the Bates numbers UDLL 000211178 through 182. Looks
20 like an e-mail string that ends up with an e-mail
21 from Lee Radtke to Val Schissel, S-C-H-I-S-S-E-L,
22 dated Friday December 14, 2007. I see no
23 highlighting --

24 A. Right.

25 Q. -- of yours on this document?

1 A. Nothing remarkable.

2 Q. And -- and you're concluding and
3 telling me that there is nothing remarkable that you
4 found in your review or rereview of previously
5 marked Exhibit M47, correct?

6 A. That is correct.

7 Q. Thank you, sir.

8 A. (Handing).

9 Q. Okay, sir. The next Mylan document
10 that you reviewed or rereviewed which you've just
11 handed me is one that was previously marked Exhibit
12 M45 bearing the number UDLL 000025489 through, looks
13 like we don't have a consecutively numbered exhibit
14 here. The first two pages are -- and it's last four
15 digits are 5489 and 5490, and then attached to that
16 is a document headed "UDL Laboratories, Inc. Quality
17 Assurance (in process)" with Bates numbers MYLN
18 000035615 through 35620. And actually it's -- that
19 document as I flip through it is out of order,
20 because I think it starts actually with 35607 and
21 continues through 35620. Anyway, tell me, I see it
22 looks like -- I'm starting to recognize your
23 handwriting here, you circled the date January 21,
24 2008, and you have written "still no Q agreement"?
25 A. It's -- it's meaningless comment. It

1 had -- nothing remarkable there. I'd have to go
2 through it to even tell you why I put that down.

3 Q. Okay. Is there anything at all
4 remarkable about this document or anything --

5 A. Not in the least bit.

6 Q. Thank you. And it -- it had no
7 influence whatsoever on your opinions?

8 A. Zero.

9 Q. By the way, we talked about UDL
10 before. In all of your preparation for your report
11 which you submitted on June 15, 2010, and in
12 preparation for your deposition on June 29, 2010 and
13 again here today on February 16, 2011, have you seen
14 anything that would indicate to you that at any time
15 that UDL tested DIGITEK tablets to make sure that
16 they were in accordance with --

17 A. I saw some -- I saw some test
18 information. I saw no exceptions. I saw no out of
19 specification test results.

20 Q. Next document.

21 A. (Hanging).

22 Q. This is a previously marked deposition
23 exhibit M39 bearing Bates stamp numbers MYLN
24 0000000381 through 385, and it looks like somebody's
25 handwriting on all of the -- all of the pages here.

1 What does this mean to you?

2 A. Nothing. There is nothing remarkable.

3 Q. Nothing remarkable and nothing about
4 previously marked Exhibit M39 which had any bearing
5 whatsoever on -- on any opinion that you rendered in
6 this case?

7 A. That is correct.

8 Q. Thank you.

9 A. (Handing).

10 Q. All right. The next document that you
11 handed me that you have either reviewed or
12 rereviewed since your deposition was first taken on
13 June 29, 2010 is a previously marked deposition
14 exhibit M-34 with Bates number MYLN 000000408, a
15 one-page document headed "recall team." Anything
16 remarkable about that document?

17 A. Not in the least bit.

18 Q. So nothing about Exhibit M34 that has
19 had any bearing on any opinion that you've rendered
20 in this case?

21 A. That is correct. (Handing).

22 Q. The next document you're handing me is
23 a previously marked deposition Exhibit M31. It
24 looks like it was marked in the deposition of
25 Mr. Adams, the deposition that you just told me that

1 you -- you had reviewed, right?

2 A. That's correct.

3 Q. And it is an e-mail from Mr. Adams to
4 a Mr. Elinski, E-L-I-N-S-K-I, dated May 13, 2008,
5 Bates numbers MYLN 000035283 through 35285.

6 Anything at all remarkable about that document?

7 A. Nothing, zero.

8 Q. Nothing that enlightened you in any
9 way?

10 A. Not in any way.

11 Q. Nothing that affected any opinion that
12 you have rendered in this case?

13 A. That is correct. (Handing.)

14 Q. The next document that you've handed
15 me that you reviewed or rereviewed since your
16 deposition was taken on June 29, 2010 is marked --
17 was previously marked as deposition Exhibit M30,
18 again, from the deposition of Mr. Adams, and it's an
19 e-mail from Mr. Adams to a number of people dated
20 May 6, 2008. Is there anything about that document
21 that you found remarkable?

22 A. Nothing remarkable.

23 Q. Enlightening?

24 A. Not in the least bit.

25 Q. So there is nothing about Exhibit M30

1 that in any way bears upon the facts or your opinion
2 in this case?

3 A. That is correct. There is -- correct.
4 (Handing).

5 Q. By the way -- and you just handed me
6 another document, and I'm going to go into that, but
7 I just want to make sure I understand this on your
8 educational background. You have a undergraduate
9 degree in engineering?

10 A. That's correct.

11 Q. What -- what specialization?

12 A. Mechanical engineering.

13 Q. And that's from what school?

14 A. University of Dayton.

15 Q. University of Dayton. Dayton, Ohio?

16 A. That's correct.

17 Q. So a guy from New Jersey goes out to
18 Ohio for school, right?

19 A. That's correct.

20 Q. All right. The Dayton fliers?

21 A. You got it.

22 Q. All right. You have no graduate
23 degree?

24 A. I do not have a graduate degree,
25 that's correct.

1 Q. Okay. You've just handed me what has
2 been previously marked as deposition Exhibit M26,
3 again, from the deposition of Mr. Adams that you
4 told me today that you reviewed but found nothing
5 remarkable in it. Here, I see your handwriting, I
6 think it says by Mr. Adams' name, executive director
7 QA at Mylan?

8 A. Yes.

9 Q. Okay. Anything about M26 that you
10 found remarkable?

11 A. Nothing remarkable.

12 Q. Or enlightening?

13 A. It did not enlighten any further.

14 Q. Or that bears in any way on any
15 opinion that you have rendered in this case?

16 A. It does not bear on any opinion.
17 (Handing).

18 Q. The good new is for the record, it
19 looks like we're getting closer to the end here.

20 A. Yeah, well, you asked for this.

21 Q. I did, I did. Well, I you didn't ask
22 for it. You just -- I did ask for it. You have
23 handed me what has been previously marked as
24 deposition Exhibit M54 with Bates numbers MYLN
25 000997539 and 7540. A document dated December 13,

1 2006 from Lee Radtke to Chuck Koons. I'll ask you
2 the same question, is there anything that you found
3 remarkable about that document?

4 A. Nothing remarkable.

5 Q. Or enlightening?

6 A. It did not enlighten me at all.

7 Q. So it had no bearing on any opinion
8 that you've given in this case?

9 A. That is correct.

10 Q. The next document that you've handed
11 me that you've reviewed or rereviewed since your
12 deposition was taken on June 29, 2010 is a two-page
13 document bearing Bates numbers MLYN 000032342 and
14 32343. It looks like a letter dated November 23,
15 2006 to Actavis from Christopher Benson, director of
16 technical purchasing at Mylan Pharmaceuticals, Inc.,
17 with an attachment regarding the fact that "Mylan is
18 an authorized distributor of record and has an
19 ongoing relationship with Actavis pursuant to a
20 written supply and distribution agreement covering
21 DIGITEK .125 milligrams and .25 milligrams." Is
22 that right?

23 A. That is correct.

24 Q. Anything remarkable about that?

25 A. No. I did not read that beforehand.

1 It appears to have established some type of legal
2 agreement, but since I'm not familiar with the
3 terms, it has no bearing whatsoever.

4 Q. Okay. And -- and this document on
5 Page 32343 refers to a written supply and
6 distribution agreement covering DIGITEK. Have you
7 seen that?

8 A. Yes, I have, sir.

9 Q. And anything about that agreement that
10 you found important?

11 A. The -- it's the lack of information
12 that I found important. It did not have the clauses
13 in it and the requirements, and it didn't establish
14 the GMP responsibilities between two parties.

15 Q. It did not establish the GMP
16 responsibilities between the two parties?

17 A. Right. It didn't deal --

18 Q. Go ahead.

19 A. It didn't deal in the specifics that
20 are required to run a business.

21 Q. Okay. What are the specifics required
22 under the law to "run a business," as you put it?

23 A. Well, you -- if -- can I pull the GMP?

24 Q. Can you pull what?

25 A. The good manufacturing practices to

1 show you what I believe can help answer that?

2 Q. Well, just answer my question.

3 A. That's the way I would answer that.

4 I'd like to read that.

5 Q. You would like to read a GMP --

6 A. Just one clause within the GMP.

7 Q. When you say "the GMP," there are a
8 lot of GMPs, aren't there?

9 A. Yeah. This is -- this is part 210 and
10 part 211. It's specifically in part 211 -- CFR part
11 211.

12 Q. Sounds like you're pretty familiar
13 with that?

14 A. I'm reasonably familiar with that.

15 Q. CFR 211?

16 A. Right. Well, I'd have to go to the
17 particular clause.

18 Q. Okay. By the way, was the supply and
19 distribution agreement a document that you reviewed
20 before your deposition was taken?

21 A. Yes, it was. I have not reviewed it
22 since.

23 Q. Was it a document that you reviewed
24 before you issued your report in this case?

25 A. Yes, it was.

1 Q. Is it a document that you have
2 referenced in your report?

3 A. I have not referenced it.

4 Q. Why not?

5 A. Because it was remarkable by its
6 absence of information. Supply agreements in -- in
7 my experience do not contain any information that is
8 associated with the details of good manufacturing
9 practices. Therefore, when I see a supply agreement
10 and I flip through it and it has nothing, no
11 attachments, no references, it's -- it's of no
12 interest to me.

13 Q. So what -- what I'm interested in and
14 what I'm going to ask you to go ahead and -- and
15 show me then is the CFR, the code of federal
16 regulations, dealing with good manufacturing
17 practices which requires Mylan to have included
18 something that you say was missing from the supply
19 and distribution agreement.

20 A. Okay.

21 Q. In its status as the distributor of
22 DIGITEK manufactured by Actavis pursuant to its
23 abbreviated new drug application approved by the
24 FDA?

25 A. I understand.

1 Q. Okay. Do you understand?

2 A. I believe so.

3 Q. All right. Show me what you've got.

4 Okay. Just for the record, you're now going outside
5 of the notebook here?

6 A. That's right. Well, I'm just pulling
7 my references.

8 Q. No, I understand, but just for the
9 record, you were going through a notebook with
10 documents pertaining to Mylan that you have reviewed
11 or rereviewed since your deposition was taken on
12 June 29, 2010, right?

13 A. That is correct.

14 Q. And now you've -- you have brought
15 another notebook here. What's the spine title on
16 that?

17 A. It says "references." It contains the
18 majority of the documents that I referenced. It
19 does not contain any additional documents.

20 Q. Okay. So when you say it contains the
21 majority of documents that are referenced, you mean
22 that are referenced in your report?

23 A. That is correct.

24 Q. And your report dated June 15, 2010
25 submitted in this case has an appendix with all of

1 the documents that you referenced in -- in arriving
2 at your opinions, right?

3 A. That is correct.

4 Q. The significant documents, right?

5 A. That is correct.

6 Q. And there are -- there are 60 of them;
7 is that right?

8 A. There are -- whatever that number is,
9 yeah.

10 Q. I'm looking at page 42, and the last
11 document listed is number 60?

12 A. Then that's it. That's correct.

13 Q. It's a two-page document, appendix B,
14 as in boy, references pages 41 and 42 of your
15 report, lists documents one through 60, right?

16 A. That's correct.

17 Q. Okay. You're handing me -- you're
18 handing me 21 CFR section 211.22 entitled,
19 "Responsibilities of Quality Control Unit; is that
20 right?

21 A. That is correct.

22 Q. Who is that directed to?

23 A. That's directed to the distributor and
24 the manufacturer.

25 Q. Where -- where do you see that it's --

1 it's directed to both the distributor and the
2 manufacturer?

3 A. It is my understanding based on my
4 experience that that is who it's directed towards,
5 that's what I used as a head of QA as my directive,
6 and it's what I would expect out of a contract
7 manufacturing company, somebody who made product for
8 me.

9 Q. Let me -- let me just make sure I
10 understand the basis here of your conclusion that 21
11 CFR section 211.22 is directed to both the
12 manufacturer of DIGITEK, Actavis, that had an ANDA
13 approved by the FDA and its distributor, Mylan. You
14 say you're referring to your own experience?

15 A. Correct.

16 Q. As head of QA. You were head of QA
17 for --

18 A. Many companies, nine different --
19 eight different companies.

20 Q. Within the Johnson & Johnson family?

21 A. Within the Johnson & Johnson family of
22 companies.

23 Q. Okay. And were any of those companies
24 distributors of a product?

25 A. Could you tell me what you are

1 describing as the distributor? Define that for me,
2 please.

3 Q. Well, isn't that what we're talking
4 about in this case?

5 A. Yeah. But I'd like to understand your
6 understanding.

7 Q. Mylan -- it's your understanding that
8 Mylan was the distributor of DIGITEK, right?

9 A. I -- if I can answer your question.

10 Q. Is it your understanding that Mylan
11 was a distributor of DIGITEK?

12 A. Yes.

13 Q. Were any of the eight Johnson &
14 Johnson family companies for whom you were the
15 director of QA distributors of a product
16 manufactured by another company pursuant to an NDA
17 or an ANDA that had been approved by the FDA?

18 A. I don't recall any.

19 Q. So you had no experience as a director
20 of QA for a company that was a distributor like
21 Mylan?

22 MS. CARTER: Object to form.

23 A. As a head of QA, I do not recall us
24 being a distributor, and I'd have to really think
25 about it. We're talking about 30 years of

1 experience in that regard. Could you give me a
2 minute? I'd like to mentally go through the
3 companies I've worked for.

4 BY MR. KAPLAN:

5 Q. Absolutely. Because I want -- I want
6 you to have your memory refreshed. I want you to
7 testify to the best of your ability here today. I
8 want you to bring all of your experience to bear,
9 and I want the jury to be able to understand --

10 A. Right.

11 Q. -- that when I say you, Mr. Kenny, in
12 all of your experience, have never been in the shoes
13 of Mylan as a distributor of a product manufactured
14 by a company like Actavis who is the holder of an
15 ANDA approved by the FDA, I want the jury to
16 understand that you have had no such experience.

17 A. Okay.

18 Q. And if that's not correct, you tell me
19 what's correct.

20 A. Okay. As the head of QA, I cannot
21 recall a product, as eight years in corporate, I did
22 audit companies, operating companies, that did
23 distribute product, market it, with -- and they did
24 not hold the ANDA or the NDA.

25 Q. Tell me about your experience.

1 A. I -- for over a period of eight years
2 on and off, I audited probably on average 20
3 companies per year worldwide.

4 Q. For whom?

5 A. Johnson & Johnson corporate.

6 Q. You -- you audited companies who were
7 distributors of Johnson & Johnson products?

8 A. I -- I audited companies that were
9 similar to Mylan in that they would distribute
10 products that they manufactured and distributed
11 products that were manufactured by another company
12 who either did -- did in some instances hold the NDA
13 or -- but mostly did not hold the ANDA or NDA.

14 Q. Tell me about -- let's go through the
15 products.

16 A. I can't recall, sir.

17 Q. Let's go through the companies.

18 A. I went to 200 companies.

19 Q. Well, give me an example of a
20 situation where you audited some company that --
21 that was in a position similar to Mylan distributing
22 a product manufactured by another company, in this
23 case, Actavis, who was the holder of an abbreviated
24 new drug application, ANDA, approved by the FDA.
25 Give me one example.

1 A. I can't recall -- I do know that I had
2 done auditing for Cilag. I did auditing -- I
3 audited them. And they were in a position where
4 they had products, and I can't recall what they
5 were, that were manufactured by the holder of an
6 ANDA or an NDA, probably an NDA, but I can't tell
7 you what -- what products they were. But I did a
8 lot of audits.

9 Q. You mentioned one company, Cilag?

10 A. Cilag.

11 Q. Can you spell that for us?

12 A. C-I-L-A-G.

13 Q. Where is Cilag located?

14 A. Schaffhausen in Switzerland.

15 Q. Is Cilag subject to FDA regulations in
16 the United States?

17 A. They do when they export product to
18 the United States.

19 Q. What did Cilag distribute in the
20 United States?

21 A. I don't recall.

22 Q. Did they distribute a product in the
23 United States?

24 A. Yes, they most certainly did.

25 Q. But you don't know what product?

1 A. I don't recall, sir.

2 Q. Who manufactured the product?

3 A. Well, they were the primary
4 manufacturer, but they used contract manufacturers
5 as --

6 Q. Well, that's a different situation
7 than Mylan, isn't it?

8 A. No. I understand, but you --

9 Q. Isn't it?

10 A. No. They did --

11 Q. Mylan is not the primary manufacturer
12 of DIGITEK, is it?

13 A. Can I explain?

14 Q. Is Mylan the primary manufacturer of
15 DIGITEK?

16 A. They are not.

17 Q. So if Cilag was the primary
18 manufacturer of some product that you can't
19 remember, it's not an equivocal situation?

20 A. No, no, no. No. Cilag did one of two
21 things, they either were the manufacturer and
22 distributor of the product of which some of those
23 products came to the United States of which when
24 I -- I audited them, I would use current GMP. They
25 also distributed product that were where the

1 holder -- the manufacturer was the holder of an ANDA
2 or an NDA. And you know, there's others, Janssen
3 Pharmaceutical, even more -- I did more for them
4 than Cilag.

5 Q. Wait a minute. You were asked to do a
6 GMP audit of a company called Cilag for your
7 employer, Janssen?

8 A. Johnson & Johnson.

9 Q. Is it Janssen?

10 A. Janssen is another company, a larger
11 company than Cilag.

12 Q. Did you audit Cilag in your capacity
13 as an employee of Johnson & Johnson?

14 A. That's correct.

15 Q. Why?

16 A. Because it was part of our
17 responsibilities is to audit all companies
18 worldwide. That was our -- our mission.

19 Q. Is Cilag a Johnson & Johnson company?

20 A. Yes, it is.

21 Q. What -- what -- what products did it
22 distribute?

23 A. I don't -- I don't recall, sir,
24 anymore.

25 Q. But you're telling me that Cilag

1 distributed products manufactured by non Johnson &
2 Johnson companies?

3 A. That is correct.

4 Q. But you don't know what -- what
5 products?

6 A. I don't recall.

7 Q. And you don't know -- you don't know
8 what other manufacturers' products Cilag
9 distributed?

10 A. I do not. I cannot recall.

11 Q. And did Cilag have a quality agreement
12 with -- with manufacturers for whom it distributed
13 products?

14 A. This was in '82. I don't recall.

15 Q. Did you ding them if they didn't?

16 A. Would I ding them? At that particular
17 point, I probably would not have.

18 Q. Did they operate under a supply and
19 distribution agreement?

20 A. The -- I don't recall.

21 Q. But you went to Switzerland to audit
22 Cilag; is that right?

23 A. That is correct.

24 Q. And it's your understanding that Cilag
25 was responsible as a distributor of a product that

1 you can't remember for a company, a manufacturer
2 that you can't remember, subject to FDA's good
3 manufacturing practice regulations?

4 A. I -- in thinking back, I probably
5 didn't ask that question of Cilag or Janssen at that
6 particular point.

7 Q. What question didn't you ask?

8 A. I did not ask to see the quality
9 agreement.

10 Q. Can you give me any other examples of
11 any experience that you've had with a company that
12 you say was in the shoes of Mylan, in other words,
13 being a distributor of a product manufactured by
14 another company, in this instance, Actavis, pursuant
15 to an ANDA approved by the FDA?

16 A. Janssen Pharmaceutical.

17 Q. Is another example?

18 A. Yes, similar to Cilag.

19 Q. Pardon?

20 A. Similar to Cilag.

21 Q. What -- what -- tell me about the
22 Janssen situation.

23 A. It would be much the same. I would
24 audit the Janssen headquarters and I -- which is
25 also the -- a manufacturing site. And I would audit

1 some of their own manufacturers and some of their
2 contract manufacturers.

3 Q. When you use the term again, "contract
4 manufacturer," and you use that in conjunction with
5 Janssen, are -- are you telling me that there were
6 instances where Janssen held an NDA or an ANDA and
7 contracted with others to manufacture the product?

8 A. That is correct.

9 Q. Is it your understanding that Mylan
10 did not hold the ANDA for DIGITEK?

11 A. It is my understanding they did not
12 hold the ANDA or NDA.

13 Q. So that's different than the Jantzen
14 situation?

15 A. In that particular situation. But
16 they also -- I'm sorry, I'm answering your
17 questions. Go ahead.

18 Q. That's -- that's fine. Getting back
19 to the CFR that you referred to, what -- what is it
20 here that you say has bearing on Mylan's
21 responsibility?

22 A. Okay. Can I read it aloud?

23 Q. Why don't you first show it to me,
24 show me exactly what it is.

25 A. (Handing). Section 22.

1 Q. Were you going to read the highlighted
2 portions?

3 A. No, the whole thing is actually
4 important. Basically what it does is tell the
5 reader that there are certain requirements for
6 quality systems that needed to be established and
7 documented, and that's it.

8 Q. Okay. Now, are you -- are you
9 familiar with GMPs that are applicable to
10 distributors of outsourced products?

11 A. The GMPs are applicable to both the
12 distributor and the person who manufactures the
13 product.

14 Q. Where -- where -- where do you derive
15 that understanding?

16 A. I derive it from that statement.

17 Q. From which statement?

18 A. The quality -- section 22.

19 Q. "There shall be a quality control unit
20 that shall have the responsibility and authority to
21 approve or reject all components, drug product
22 containers, closures, and processed materials." Is
23 that the statement?

24 A. Yes.

25 Q. And you think that applies to both

1 manufacturers and distributors?

2 A. I know it does.

3 Q. How do you know that?

4 A. Because that's the way I was trained.

5 Q. Can you show me something in -- in the
6 regulations here that says this is applicable to
7 distributors and to manufacturers of products that
8 are approved by the FDA pursuant to an ANDA or an
9 NDA?

10 A. I am not a legal expert. I cannot
11 point to that.

12 Q. So if you are wrong, then, if this
13 only applies to a manufacturer and not a
14 distributor, that would affect your opinion?

15 A. I am not wrong, but it would.

16 Q. Are you familiar with the distribution
17 procedures that are set forth in the GMPs?

18 A. Reasonably familiar, but I always
19 reread them to refamiliarize myself when I have
20 questions.

21 Q. The regulation that you were referring
22 to is part of section two --

23 A. Do you want me to give you the
24 specific thing?

25 Q. Let me just see that.

1 A. Sure. Let me turn the page for you.

2 Q. So, you are also familiar with, I take
3 it, 21 CFR 210.1 regarding the status of good
4 manufacturing practice regulations?

5 A. I have to reread it.

6 Q. Well, I'll just -- I'll read you
7 section A under section 210.1, and ask you whether
8 you agree with this. The regulation set forth in
9 this part and in parts 211 through 226 of this
10 chapter, "contain the minimum current good
11 manufacturing practice for methods to be use in and
12 the facilities or controls to be used for the
13 manufacture, processing, packing, or holding of a
14 drug to ensure that such drug meet the requirements
15 of the act as to safety and has the identity and
16 strength and meets the quality and purity
17 characteristics that it purports or is represented
18 to possess." Does that sound familiar to you?

19 A. Yes.

20 Q. Okay. That's the manufacturer's
21 responsibility, isn't it?

22 A. That is the manufacturer's or the
23 distributor's responsibilities.

24 Q. And -- and again, with all due
25 respect, sir, where do you see that that is a

1 distributor's responsibility?

2 A. I did not see that word in there. It
3 is my understanding that it does include a
4 distributor of the product.

5 Q. And that understanding is derived from
6 what?

7 A. From my experience and my training.

8 Q. In all of the documents you reviewed
9 regarding FDA inspections regarding DIGITEK, did you
10 ever see the FDA inspect Mylan?

11 A. No, I did not.

12 Q. Why not?

13 A. I don't know, you have to ask them. I
14 don't know.

15 Q. Well, you have a lot of experience,
16 don't you?

17 A. I have experience but not as a -- from
18 an FDA standpoint. And whether they were audited or
19 not, I don't know. Perhaps they were audited or
20 inspected.

21 Q. Did you see anything that -- that led
22 you to believe that the FDA was ever critical of
23 Mylan?

24 A. I didn't see any reference to Mylan
25 where there was criticism.

1 Q. By the FDA?

2 A. By the FDA.

3 Q. Okay. Moving right along with your
4 book here of the Mylan documents that you reviewed
5 or rereviewed since your deposition was initially
6 taken on June 29, 2010, please hand me the next
7 document.

8 A. This really is -- well, it's basically
9 the same. Let me show you it to you. It's an
10 unsigned version of a -- of a similar subject.

11 Q. It may be in fact exactly the same.

12 A. It may be.

13 Q. It bears the Bates number -- it's a
14 one-page document with Bates number MLYN 000032343,
15 which was I believe the second page that was
16 attached to the earlier document, right?

17 A. I am sure that's right.

18 Q. Okay. So, again, there is nothing
19 here that's remarkable to you?

20 A. Nothing.

21 Q. Nothing that bears upon your opinion?

22 A. Correct.

23 Q. Nothing that you found enlightening?

24 A. No, nothing enlightening.

25 Q. Okay. In all of your experience,

1 let's go back to that situation you were describing
2 to me before about a company called Cilag.

3 A. Cilag.

4 Q. C-I-L-A-G, and Janssen, were they
5 considered authorized distributors of record?

6 A. I don't know what legally they were
7 categorized as.

8 Q. So how would you conduct an audit of
9 those companies without knowing what their legal
10 status or -- or the requirements were?

11 A. Based upon my training, they were
12 required to meet all aspects of the GMPs, so the
13 compliment of the two companies had to meet every
14 requirement.

15 Q. Fundamental to your opinions in this
16 case is the legal status of the party involved,
17 right?

18 A. I'm not sure if it is.

19 Q. Well, the legal status of the party
20 involved carries with it certain legal requirements,
21 doesn't it?

22 A. But this is going beyond what I am
23 looking at. I am looking at, based upon my
24 training, what the expectation is from the FDA and
25 business norms, expected business norms, what the

1 control systems that should be in place to meet all
2 aspects and conditions of GMP.

3 Q. When you refer to "business norms,"
4 what's -- what's the foundation for your arriving
5 at, quote, what "business norms" are?

6 A. When I review a company and I review
7 for business norms, I would recommend to them
8 perhaps improvement based upon benchmarking other
9 companies. It wouldn't be an observation, it would
10 be part of continual improvement process.

11 Q. Just refer me to the underlying
12 documents that establish the business norms in your
13 area of expertise.

14 A. It would be my informal understanding
15 of best practice.

16 Q. Is there any document whatsoever that
17 establishes "business norms"?

18 A. Absolutely nothing.

19 Q. This is all kind of up in your head,
20 right?

21 A. When it comes to success models, it is
22 in my head based upon the companies or experience
23 that I've had.

24 Q. So -- so when you -- so when you use
25 the term and you refer to business norms, that's

1 whatever Kenny says the norm shall be?

2 A. That is what -- in that regard, I
3 wouldn't put it that way, but I understand your
4 question, and I would say, yes, it's based upon
5 my -- it's -- it's much like a consultant going in
6 and saying it does not necessarily violate GMP, but
7 it's a good thing to do.

8 Q. It is twelve o'clock. Do you want
9 to --

10 A. I'll tell you if I'm not holding up
11 well.

12 (Handing.) This is much the same.

13 Q. Okay. You've just handed me another
14 document that you've reviewed or rereviewed since
15 your deposition of June 29, 2010. And it is a
16 previously marked Exhibit M-7 from the deposition of
17 Susie Wolf that bears Bates numbers MYLN 000032473
18 through 75. By the way, you did not read the Susie
19 Wolf deposition, did you?

20 A. Susie Wolf. I don't recall. I'd have
21 to -- I did not reread it, perhaps I read it earlier
22 and I found nothing --

23 Q. Wait a minute. Wait a minute. In
24 your previous deposition, you said the only Mylan
25 deposition you read was Chuck Koons. Earlier today

1 you said oh, no, no, I was mistaken. I think I read
2 Mike Adam, and at least I reread Mike Adams. That's
3 one of the documents here. And then I said, well,
4 have you read any other Mylan depositions, and you
5 said no.

6 A. And your question is?

7 Q. You haven't read any other Mylan
8 depositions, have you?

9 A. No, I have not read Susie Wolf's
10 deposition.

11 Q. Is there anything about this document
12 marked Exhibit M7 that you found remarkable?

13 A. Nothing.

14 Q. Nothing enlightening?

15 A. Nothing enlightening.

16 Q. Nothing that bears on any opinion that
17 you have rendered in this case, right?

18 A. That is correct.

19 Q. The next document that you have handed
20 me is marked Exhibit M8. Also from the deposition
21 of Susie Wolf, with Bates numbers MYLN 000032477
22 through 79. It looks to me like your handwriting on
23 the front. It says "done" with a big red checkmark?

24 A. It just means I've read it.

25 Q. And then you've got a line through the

1 first page, right?

2 A. Yes.

3 Q. And what -- what -- and then you put a
4 big checkmark on the second page?

5 A. Yes.

6 Q. You have a circle with a question mark
7 on it?

8 A. I don't know what that meant. That
9 was reviewed a while back.

10 Q. So I take it there's nothing about
11 this Exhibit M8 that you found remarkable,
12 enlightening, or had any bearing upon any opinions
13 that you've given in this case?

14 A. That is correct. Do you want to see
15 things that I had read that are not --

16 Q. Well, I want to know what it is that
17 you have done since your deposition was taken on
18 June 29, 2010 by way of research, review, testing,
19 discussions with counsel, anything that you've done
20 that you think, you know, was significant or not
21 significant. I don't care. I just want to know
22 what you've done.

23 A. But if I reread a document to
24 familiarize myself with it, it didn't change
25 anything, you have no interest in looking at it.

1 Q. Unless there was something significant
2 or you learned something or it reinforced --

3 A. All of these were that.

4 Q. When you say all of these were, we're
5 getting toward the end here?

6 A. Yeah. We head towards the end, it's
7 kind of like anything else, either I have read it,
8 and you know, I understand it, et cetera, and I've
9 factored that in accordingly into my expert opinion
10 or my report.

11 Q. And if it was really significant, it
12 would be among the 60 documents that you have listed
13 in appendix B to your report of June 15, 2010 as the
14 referenced documents, correct?

15 A. That is correct. And -- so that's
16 what we're going through now. It's kind of the tail
17 ends of this. That's why --

18 Q. Okay. Well, we can do this. In -- in
19 the tail end of these documents that are in this
20 notebook, is there anything that jumps off the page
21 at you?

22 A. I really would like to look at it to
23 make sure I can answer that.

24 Q. Okay. And you know what I mean by
25 that?

1 A. I know exactly what you mean.

2 MS. CARTER: Do you want him to do
3 that during lunch?

4 A. It will only take me a couple of
5 minutes.

6 MR. KAPLAN: Why don't we do that
7 right now, and then we can get through this
8 notebook, and then we'll move on to another
9 subject after lunch. We'll stay on the
10 record.

11 A. To answer your consistent question,
12 there is nothing remarkable, and it had no effect,
13 the new documents had no effect on my report.

14 Q. Okay. And of these remaining
15 documents, tell me which ones are new to you.

16 A. Well, a lot of them have to do with
17 UDL. And again, as I explained, my process was to
18 just print these up. And so I just -- when in
19 doubt, I printed them, I looked at them. If there
20 is nothing remarkable, there is zero on it. If
21 there was something remarkable, there may be a note,
22 even that may have no importance.

23 Q. Okay. So there is no either new
24 document pertaining to Mylan that you reviewed since
25 your deposition of June 29, 2010 or any old Mylan

1 document that in any way was remarkable to you?

2 A. There was nothing.

3 Q. All right. How about some lunch?

4 A. Sounds good.

5 Q. Not here yet. Okay. Well, we can
6 take a restroom break and relax a little bit.

7 A. Do you want to take a short lunch?

8 THE VIDEOGRAPHER: We're off the
9 record. The time is --

10 THE WITNESS: Do you want to continue
11 until lunch.

12 BY MR. KAPLAN:

13 Q. I'm good to go. Are you good to go?

14 A. I'll raise my hand.

15 Q. Okay. You raise your hand. I told
16 you earlier I don't want to put you --

17 A. It's a challenge.

18 Q. I don't want to put you through
19 anything unnecessarily. Okay. Let's -- let's do
20 this: Remember at the end of your deposition on
21 June 29, 2010, I simply asked you to make sure that
22 you went through the documents you were requested to
23 bring to your deposition, which you hadn't brought
24 in their entirety the first time around. And I
25 said, now, I'm going to have a chance to examine

1 you, and I want to make sure you bring everything
2 with you?

3 A. Which I have.

4 Q. Okay. So let's go through the
5 documents requested in the amended notice of the
6 video deposition. This is what we call like a
7 subpoena duces tecum, in other words, the witness is
8 requested to bring these documents. And you told me
9 you would do that, and now you're telling me you
10 have brought them, right?

11 A. That is correct.

12 Q. Okay. So number one asks for your
13 current curriculum vitae or résumé.

14 A. Right.

15 Q. Is there anything -- it's in that
16 report, isn't it?

17 A. That's it.

18 Q. And that's it?

19 A. Yes.

20 Q. So what -- what is on your CV in the
21 report of June 15, 2010 is accurate, right?

22 A. That is correct.

23 Q. And it's up-to-date, right?

24 A. That is correct.

25 Q. All right. We'll -- we'll go through

1 some of that --

2 A. Let me make sure it's up-to-date, sir.

3 Q. Actually, you say in your report on
4 Page 3, that your complete CV is at appendix A of
5 your report, so that would be on page 37 and 38, 39,
6 40. So 37 through 40, that is your CV, right?

7 A. Yes. And that is a complete CV. Same
8 as what I brought here (indicating).

9 Q. Okay. Number two asks that you bring
10 all correspondence and communication between the
11 witness, you, or anyone acting on the witness'
12 behalf, and attorneys representing plaintiffs in
13 this Digitek litigation. So have you brought that?

14 A. Could you repeat that? I'm sorry. I
15 was reading.

16 Q. Okay. You -- you have had this --

17 A. I have had that, and I went through it
18 line by line.

19 Q. And I think Meghan told me you did. I
20 appreciate you your being conscientious about that.
21 Correspondence and communication between you, the
22 witness, or anyone acting on your behalf.

23 A. Yes.

24 Q. And anyone else from SpyGlass or any
25 of your partners or business associates, and

1 attorneys representing plaintiffs in this
2 DIGITEK litigation.

3 A. That's correct.

4 Q. Okay. Do you have that
5 correspondence?

6 A. Oh, yeah. Oh, I thought you started
7 going through it. It's going to take me a couple of
8 minutes just to -- I mean, I have three volumes of
9 this stuff. (Handing.)

10 Q. Okay. By the way, you work pretty
11 closely with your colleague, Sal Romano, in this
12 case?

13 A. I do at times.

14 Q. You did in this case?

15 A. Initially I did.

16 Q. Well, you did up until ten days before
17 you issued your final opinion, didn't you?

18 A. If that's the date. I -- perhaps it
19 was ten days.

20 Q. But you and Sal Romano collaborated on
21 the expert opinions that finally came out under your
22 name, right?

23 A. Yes. He was basically a consultant to
24 me, if you will, and then it was determined that --
25 originally we had discussed both of us signing a

1 deposition.

2 Q. Signing the report?

3 A. Signing the report, rather, and he
4 felt he could not meet the legal schedule and
5 therefore had to -- had to pull back.

6 Q. But he was your partner in -- in
7 getting to --

8 A. I wouldn't use the name "partner," but
9 he participated.

10 Q. He was part of the SpyGlass group?

11 A. Part of the SpyGlass group.

12 Q. He has billed for his time?

13 A. That -- that is correct.

14 Q. At \$430 an hour as well, right?

15 A. That is correct.

16 Q. So essentially, the Plaintiff's
17 lawyers got two for one here, right, but charged
18 separately?

19 A. Or one for two, but yeah.

20 Q. Yeah. So between the two of you,
21 that's \$860 an hour?

22 A. When we work -- yeah, right. If we
23 work together, it would be -- it would add up to
24 that.

25 Q. \$860?

1 A. Yes.

2 Q. Okay. And did you bring the -- the
3 correspondence between you and Sal?

4 A. I brought all of the correspondence
5 between Sal and I, yes.

6 Q. Oh, did you? Okay. Is that in this
7 folder here?

8 A. That would be in the e-mails.

9 Q. Okay. So I have a folder here, and
10 I'm going to ask the court reporter to mark it as
11 Exhibit 110.

12 (Whereupon, Exhibit 110, Folder, was
13 marked for identification as of today's
14 date.)

15 BY MR. KAPLAN:

16 Q. So this folder labeled "e-mails,"
17 which has been marked as Exhibit 110, contains all
18 the correspondence between you and any of the
19 Plaintiff's lawyers for whom you are working here?

20 A. That is correct.

21 Q. And between you and Sal Romano?

22 A. That is correct.

23 Q. And who else collaborated on -- on
24 your opinions in this case?

25 A. Nobody else.

1 Q. You had mentioned another person at
2 the deposition on June 29, 2010 who engaged you or
3 introduced you to the Motley Rice firm.

4 A. Yeah, John Kowalski.

5 Q. And who is John Kowalski?

6 A. I worked with John 30 years ago, 25
7 years ago, and he's -- I think he has his own
8 independent consulting company.

9 Q. Okay. What was his role in this case?

10 A. Giving us a telephone number of who to
11 call.

12 Q. So he didn't participate
13 substantively?

14 A. Not in the least bit. I didn't even
15 talk to him.

16 Q. And he hasn't billed for any of his
17 work in this case?

18 A. No, he has not.

19 Q. Okay. How about Russ Somma,
20 S-O-M-M-A?

21 A. Yeah.

22 Q. Okay. Was he part of your team?

23 A. No, he was not part of the group.

24 Q. Who is Russ Somma?

25 A. Russ Somma is an independent

1 consultant who is an expert on tableting, among
2 other things.

3 Q. Well, didn't you recommend to the
4 plaintiff's lawyers in this case that Russ Somma be
5 included as part of the, quote, evaluation team?

6 A. We recommended -- we offered his name
7 as somebody that based upon our research, was
8 qualified.

9 Q. And you recommended that Russ Somma be
10 part of the "evaluation team," right?

11 A. No, I would not say that. I
12 recommended that they talk to him. I don't have
13 first-hand --

14 Q. You did say that, didn't you?

15 A. What's that?

16 Q. Well, I'm looking at an e-mail here,
17 and I'm going to show it to you, from SpyGlass
18 Group, Inc., that's you?

19 A. Yeah.

20 Q. Dated March 23, 2010 to Meghan Johnson
21 Carter, that's Meghan sitting here, and Sal Romano,
22 with copies to Sandy Summers, Fred Thompson, Pete
23 Miller, and SpyGlass Group, Inc., subject, drug
24 tableting expert. And it says -- you tell me if I'm
25 wrong -- I'm going to show it to you. "I recommend

1 that you consider Russ Somma as part of the
2 evaluation team."

3 A. Yes, I said that, I'm sure. I mean,
4 it's in there, and I did recommend that they
5 consider him, that based upon -- I'm sorry, go
6 ahead.

7 Q. Go ahead.

8 A. No.

9 Q. What else did you want to add? What
10 happened with Mr. Somma?

11 A. They engaged him and had a contract
12 with him and they engaged him.

13 Q. So is he part of the evaluation team?

14 A. He's not part of any team that I'm a
15 part of.

16 Q. Well, did he participate in the work
17 that you and Sal Romano did in arriving at opinions
18 in this case?

19 A. No, zero, absolutely zero.

20 Q. Mr. Romano is a PhD, is he?

21 A. That is correct.

22 Q. And what does he have his PhD in?

23 A. Analytical chemistry.

24 Q. And he is the vice president of the
25 SpyGlass Group?

1 A. He's a vice president of the SpyGlass
2 Group, that's his title.

3 Q. And you are the managing director of
4 the SpyGlass Group?

5 A. That is correct.

6 Q. That is a corporation?

7 A. That is a corporation.

8 Q. That does work as expert witness in
9 litigation?

10 A. That does consulting work.

11 Q. And work as expert witness in
12 litigation?

13 A. Recently. Recently.

14 Q. Actually, the expert witness work is
15 more lucrative than the consulting work?

16 A. It gets billed at a higher rate when
17 it's billed.

18 Q. When you worked for Johnson & Johnson,
19 were you paid \$430 an hour?

20 A. No, I was not.

21 Q. How much were you paid per hour?

22 A. I don't know. I made on average a
23 quarter of a million dollars a year. You figure out
24 per hour what that is since 1990.

25 Q. It wasn't 430 an hour?

1 A. I have no idea. I'd have to
2 extrapolate it out. It was probably 5 cents an hour
3 based upon the number of hours that I worked.

4 Q. Okay. So what was Mr. or Dr. -- is it
5 Dr. Romano?

6 A. Yes.

7 Q. What was Dr. Romano's role?

8 A. Originally it was to offer expert
9 opinion.

10 Q. On what?

11 A. On this, the case that I worked on
12 that -- that we're discussing today.

13 Q. Okay. You have different areas of
14 expertise?

15 A. Yes, that is correct.

16 Q. Your expertise you say is in --

17 A. Quality systems.

18 Q. Quality systems. And his expertise is
19 in?

20 A. His expertise is in the laboratory and
21 in managing a world-class company from a corporate
22 standpoint.

23 Q. What world-class company did he
24 manage?

25 A. Johnson & Johnson. He was the head of

1 quality and compliance services for, I don't know,
2 10 years or so at the company.

3 Q. What -- what did he contribute to the
4 opinions that you rendered in your report of
5 June 15, 2010?

6 A. Could you -- can I ask you to rephrase
7 that? And it's an important question. Rephrase it.

8 Q. I'll have the court reporter to ask it
9 back again and you tell me.

10 (Record read.)

11 A. Nothing.

12 Q. Well, what did he bill for?

13 A. He billed for review, as I billed for
14 review.

15 Q. What was his review?

16 A. His review -- he reviewed the same
17 things that I reviewed.

18 Q. So you worked kind of in double
19 harness?

20 A. Correct. We were in parallel.

21 Q. But you didn't find his input helpful
22 to you in arriving at opinions?

23 A. I found his -- his opinions helpful
24 and that they reinforced what I understood to be the
25 business, and I understood the requirements. He did

1 reinforce my opinion. In other words -- yeah,
2 that's it.

3 Q. What -- what -- what opinion did he
4 reinforce for you?

5 A. Depends upon the section of the
6 document. He read my report and then we discussed
7 it. As a matter of fact, you have a copy of the
8 report where we met and he read, and you know, he
9 gave me his input. Most of it was typing and
10 spelling kind of thing.

11 Q. He helped you write the report?

12 A. He assisted. I would have to say yes,
13 yes.

14 Q. How did he help you write the report?

15 A. Well, he participated in it.

16 Q. Who was the original drafter of the
17 report?

18 A. I am. I am the drafter. I am the
19 writer. He was a reviewer.

20 Q. Meghan was a reviewer?

21 A. No, Meghan didn't review anything.

22 Q. She didn't?

23 A. No.

24 Q. Never did?

25 A. Oh, yeah. I sent her one copy, I

1 don't know, towards June 3rd or something like that.
2 She reviewed a copy on June 3rd, never saw -- never
3 saw a single document other than I flashed in front
4 of them the first document that I was working on,
5 that I was working on.

6 Q. When you say "I flashed in front of
7 them" --

8 A. Flashing, meaning we had a meeting,
9 very first meeting --

10 Q. Who is we?

11 A. Sal Romano and myself, Pete Miller and
12 Meghan. We had a meeting and they asked me how is
13 it going? And I said fine. And I gave them my
14 approach and I said my approach is very analytical.
15 I don't jump to conclusions, but I logically go
16 through it, and at the end of it, I will make some
17 type of a conclusion. And I showed them what I was
18 working on, I'm taking all of the facts, I'm
19 compiling them, I'm organizing them, which
20 ultimately became the tables or some edits became
21 the tables. And based upon that which was the first
22 draft of my report, then I started adding meat to
23 the report narrative. And at that point, Sal would
24 review the narrative. We met twice.

25 Q. When was it that you said you -- you

1 met with Meghan Carter and Pete Miller to show them
2 your report?

3 A. I'd have to go through the e-mail, but
4 it -- it should be there.

5 Q. But -- but you didn't meet with them
6 before your report was finalized?

7 A. Yes. That is correct.

8 Q. And they reviewed that report?

9 A. They did not review the report, they
10 didn't even look at it. They didn't see a word in
11 it, nothing, zero. I had -- I had something right
12 here, I'm explaining, please.

13 Q. Okay. Sure.

14 A. This is very important, I understand
15 that. I had a document which is quite similar to
16 the attachments that are in there (indicating),
17 which you have electronic copies of and you have
18 electronic copies of every single change that I made
19 because I was really particular about it, okay? I
20 had that document here (indicating), and they said
21 what -- how are you doing? I said I am reviewing
22 it. I said I'm compiling it. I said here is my
23 approach. Is it -- I asked them if it was logical,
24 and they said sure, go for it.

25 Q. So they didn't review -- Meghan Carter

1 or Pete Miller did not review your report?

2 A. Sir, I will answer this again, but
3 it's not necessarily to repeat it. They looked at
4 no report other than the June 3rd or whatever it
5 was, report, and that was it.

6 Q. Okay. So they looked at a report on
7 June 3rd?

8 A. June 3rd, yeah, or thereabouts.

9 Q. The Plaintiff's lawyers did?

10 A. Yes.

11 Q. They reviewed the report that you gave
12 them on June 3rd?

13 A. That is correct.

14 Q. And they had input into your final
15 report, didn't they?

16 A. They had some wordsmithing assistance.

17 Q. They -- they gave you direction as to
18 what -- what should be said in the final report?

19 A. No. They challenged me, quite
20 honestly. They challenged me as to whether or
21 not -- they said, remember, and they gave me some
22 rules, if you will, as an expert that all of your
23 opinions have to be based upon facts and data and
24 experience. And I wanted to make sure that I
25 wasn't, you know, shooting from the hip. So it was

1 really to -- just to make sure I wasn't over
2 extending my -- my expert experience.

3 Q. They told you that all of your
4 opinions had to be based on facts, data, and what,
5 research?

6 A. Well, I'm paraphrasing. They
7 didn't -- we didn't discuss it that way, but the way
8 I interpreted it is that my opinion need to be based
9 upon my expert -- or the experience that I had which
10 would render me a -- an expert witness. And that --
11 yeah, sorry.

12 Q. And -- and you got specific direction
13 from the plaintiffs' attorneys as to what should be
14 contained in the report, didn't you?

15 A. I -- no. I had some I would say
16 grammar -- Meghan, if I recall, just -- it was
17 grammar. I don't think there was anything else.
18 And I believe there might have been a discussion
19 with Pete on whether or not I -- that's an expert
20 opinion or is that your opinion? And I changed, I
21 don't know, a paragraph, two paragraphs, if that,
22 and rephrased it. I'll give you an example.

23 Q. You're kind of rambling and -- and
24 you're going beyond the question I asked you.

25 A. Sure. Go right ahead.

1 Q. You got substantive input from the
2 Plaintiff's lawyers on what should be contained in
3 your opinion.

4 A. I would not call that substantive.
5 No, I did not get substantive opinion or direction.

6 Q. So it's your testimony, then, you got
7 no substantive direction from any of the Plaintiff's
8 lawyers as to what should be contained in your
9 report of June 15, 2010?

10 A. Yes. Thank you for phrasing it that
11 way. Yes, that is correct.

12 Q. No Plaintiff's lawyer told you
13 anything about what you should say as to Mylan?

14 A. Absolutely not, zero.

15 Q. Let's -- why don't we -- why don't we
16 break now. It's 12:30 and we'll have lunch and
17 we'll come back.

18 THE VIDEOGRAPHER: We're off the
19 record. The time is 12:34. This is the end
20 of tape 2.

21 (Luncheon recess taken.)

22 A F T E R N O O N S E S S I O N

23 (1:33 p.m.)

24

25 THE VIDEOGRAPHER: We're back on the

1 record. The time is 1:32. This is the
2 beginning of tape 3.

3

4 M A R K G. K E N N Y, resumed having been
5 previously duly sworn, was examined and testified
6 further as follows:

7

8 EXAMINATION (Cont'd.)

9 BY MR. KAPLAN:

10 Q. All right. So we were just asking you
11 about -- I was asking you about the preparation of
12 your report and whether or not you got substantive
13 input and direction from the Plaintiff's lawyers.

14 A. Uh-huh.

15 Q. And your answer to that?

16 A. Absolutely no substantive information,
17 direction, of any sort.

18 Q. Okay. And I'm going to ask you
19 whether you got substantive input and direction in
20 the preparation of your report from Sal Romano?

21 A. No, I did not.

22 Q. Did not?

23 A. Did not. The report is my report.

24 Q. He had no input into it?

25 A. We discussed it. Did he have input

1 into the report? No. Because the report is mine,
2 has to be in my words. It has to be in my belief
3 system, and that's what is in this report.

4 Q. Did Mr. Romano give you direction as
5 to things that you should include in your report
6 that you didn't include in previous drafts?

7 A. Nothing, zero.

8 Q. And likewise as to the Plaintiff's
9 lawyers, did the Plaintiff's lawyers give you any
10 direction or input as to matters that should be
11 included in your final report that weren't included
12 in previous drafts?

13 A. No.

14 Q. And you're sure of that?

15 A. I'm sure of that.

16 Q. Let's just -- let's continue marching
17 through the documents that you were requested to
18 bring today and see what we have. You gave me the
19 correspondence and communication that you have had
20 with the Plaintiff's lawyers and other people with
21 whom you've been working, including Mr. Romano?

22 A. Correct.

23 Q. Number 3, all other documents prepared
24 by the attorneys for the plaintiffs and sent to the
25 witness?

1 A. Say that again, sir.

2 Q. All other documents prepared by the
3 attorneys for the plaintiffs and sent to the
4 witness?

5 A. Yes, I have -- I need to look through
6 that, but I have the e-mails.

7 Q. What do you need to look through?

8 A. I don't know if I threw them all in
9 there or not.

10 Q. Are they in here or are they not in
11 here?

12 A. Well, I don't know. I just want to
13 check.

14 Q. Okay. I have flagged some things --

15 A. Are those all of the e-mails? If they
16 are all e-mails, then -- because I have a letter, a
17 contract letter, and I think that's pretty much it.
18 Would you like me to --

19 Q. Just look and see whether other than
20 this file that has been marked as Exhibit 110,
21 whether there are any other documents that you
22 brought with you today that constitute other
23 documents prepared by the attorneys for the
24 plaintiffs and sent to you.

25 A. You mean -- does that include -- I

1 gave you a CD of -- a copy of a CD with documents
2 that were sent to me. Those were primarily
3 plaintiff documents. I think all of them may have
4 begin with a P. You have that copy of that.

5 Q. You gave me two disks this morning.

6 A. Correct.

7 Q. Okay. And you're saying that any
8 documents that you received from plaintiffs other
9 than the e-mail correspondence would be on -- on
10 those two disks?

11 A. That's correct.

12 Q. Okay.

13 A. Do you want me to look, further look?

14 Q. Well, we're here today to take your
15 testimony and to make sure that I have in front of
16 me all the items that were requested so that I can
17 ask you questions.

18 A. (Handing.)

19 Q. You're handing me a pile of documents
20 here that you are indicating would be responsive to
21 the request for documents prepared by attorneys for
22 the plaintiffs and sent to you?

23 A. No. Those are -- those are
24 communications. I didn't get anything of documents
25 that were prepared by them other than a contract --

1 that's it. That's the only thing that I received.

2 MR. KAPLAN: Let's mark as Exhibit 111
3 this document.

4 (Whereupon, Exhibit 111, Chronology
5 from disks, was marked for identification as
6 of today's date.)

7 BY MR. KAPLAN:

8 Q. I will just say for the record that
9 this came from one of the disks that you gave me,
10 and the cover on that says, "Host name:
11 172.17.66.179." And then user name AMW. I don't
12 know what that means. And then job X10000012.XLS,
13 date and time, 2/16/11, 9:49. Was that -- oh,
14 that's us printing, okay. All right. At 9:49 this
15 morning. It was described as Motley timeline,
16 5/5/2010.

17 A. Okay.

18 Q. Does that ring a familiar note to you?

19 A. I have several versions of this
20 document.

21 Q. All right. Identify for the record
22 Exhibit 111.

23 A. Exhibit 111 does not have a title. It
24 is -- appears to be or it is, a chronology that I
25 made based upon documents as I saw them. So I tried

1 to understand the sequence of events.

2 Q. Why does it say Motley timeline?

3 A. Oh, why? Because it was associated
4 with Motley, it had nothing to do with them. They
5 did not originate this. They didn't even see it.

6 Q. Okay. Mylan is not mentioned in
7 Exhibit 111, is it?

8 A. Mylan is not mentioned, that is
9 correct.

10 Q. From the group of documents that you
11 just gave me, and I'm just going through them for
12 the first time here. I'm going to mark this, but I
13 want to read this to you and -- and I'm going to ask
14 you about it. Something I just noted here is an
15 e-mail from Sal Romano to Meghan Johnson Carter with
16 a copy to SpyGlass, that's you, subject Re first
17 draft, and it says, "Meg, Mark and I" -- you're
18 Mark, right?

19 A. Uh-huh.

20 Q. "Mark and I were expecting to hear
21 from you today with your edits. Mark will make the
22 final corrections tomorrow. Can he e-mail you a
23 copy and send the signed copy at a later date?
24 Thanks, Sal."

25 A. Right. That had to do with the --

1 with the documents that you've seen, which you have
2 copies of. So he's talking about the document that
3 I am creating. See, Sal originally was --

4 Q. Wait, wait, wait.

5 A. Sure. Go ahead.

6 Q. There's no question pending right now.
7 Okay. Again, with all due respect, you -- you have
8 to just slow down and answer my question, just my
9 question, okay?

10 A. I understand.

11 Q. Okay. So Sal says on June 14th, the
12 day before you signed the report that you and he
13 were expecting to hear from Meg, who is sitting here
14 today, Meg -- Meghan Carter, the Plaintiff's
15 attorney, to get her edits to your report, right?

16 A. That's correct.

17 Q. So does that now refresh your
18 recollection and change your testimony that you gave
19 earlier that you did not get input and direction
20 from the plaintiff's attorney as to the content of
21 your report?

22 A. No. I explained earlier that Meghan
23 gave me spelling corrections. There was no content
24 change as a result of our -- our working together,
25 none, zero.

1 Q. Okay. So the only thing that -- that
2 the Plaintiff's lawyers did was check your spelling?

3 A. Yes, basically.

4 Q. And that's what you were waiting to
5 hear from them with regard to your spelling?

6 A. No. That is not -- what I said is not
7 correct with Meghan. With another conversation, the
8 wording that I had used, they -- they said -- you
9 have to ask yourself a question, whether or not --
10 and I'd have to read the statement, but basically
11 it's -- let me read it. And this is not part of my
12 vocabulary.

13 Q. What are you referring to?

14 A. It is my -- looking in the expert
15 witness, I repeated this phrase many times, looking
16 at page 35, the second paragraph (indicating).

17 Q. With all due respect, let's go back to
18 my question, because I think you kind of brushed
19 over it. Let's just repeat the question and then --
20 and then let me have your response.

21 MS. CARTER: I think he's trying to
22 answer it though.

23 A. I'm trying to.

24 MR. KAPLAN: Okay. Well, let's see.
25 Ask him the question again, and let's see.

1 (Record read.)

2 A. It does not change what I said.

3 BY MR. KAPLAN:

4 Q. Okay. That's the only question I
5 asked you.

6 A. Okay.

7 Q. And did you tell me that Russell Somma
8 was not involved in the --

9 A. Russell Somma was -- I was not
10 involved with Russell, the work that he did.

11 Q. Was he involved with you?

12 A. Only through an introduction.

13 Q. Okay. Well -- and -- and I'm happy to
14 show you this too, but again, in this pile of
15 documents that you just handed me, I see an e-mail
16 from Russell Somma dated May 14, 2010. That's a
17 month before you submit your final report of
18 June 15, 2010?

19 A. Right.

20 Q. To SpyGlass Group, that's you, and to
21 Sal Romano.

22 A. Okay.

23 Q. Re meeting with Motley Rice and Pete
24 Miller. Motley Rice is Meghan, right?

25 A. Yes. That was -- that was a -- over

1 the phone, I believe.

2 Q. And the e-mail says Mark --

3 A. I was never with him.

4 Q. "Mark, Sal, let's do a TC," telephone
5 call, "Saturday, easier for everyone I think. Plan
6 for 9 a.m. for a half hour, call in." And it gives
7 the number. "Speak with you both then, Russ."

8 A. And it had -- yes. I don't remember
9 the exact conversation, but I do remember that we
10 talked over the phone. Actually, I'm not sure that
11 actually happened, but it probably did.

12 Q. And so you had Russell Somma's input
13 and direction in shaping the expert report of
14 June 15, 2010?

15 A. Absolutely nothing. He had no input.

16 Q. So when Russell Somma says to you in
17 his e-mail of May 12, 2010, "Sal, Mark, met with
18 these folks until nine last night. I requested some
19 further information and generally reviewed what the
20 expert report will be speaking to. We need to
21 coordinate our efforts for sure. Let me know when
22 you guys want to talk."

23 A. Right.

24 Q. "We can set up regular meetings for
25 review of progress."

1 A. Right.

2 Q. What do you think he meant?

3 A. Originally, we thought that our
4 approach was going to be he takes a certain portion
5 of the operations, and then we don't duplicate that
6 work and do the rest of it. As it turned out, we
7 had no collaboration whatsoever, zero. It was -- it
8 was a theoretical model, if you will, that we went
9 into this that, you know, you take the left, I take
10 the center and the right. And -- and as it turned
11 out, we became -- since he was not part of the
12 SpyGlass Group, I did not want to assume any
13 liability or whatever for what he did, so we became
14 100 percent independent at that point.

15 Q. So he worked with you up until May 14,
16 2010, and then you cut him loose?

17 A. No. We had -- originally, we thought
18 that he would -- no. To answer your question, no.

19 Q. Did he work with you up until May 14
20 of 2010?

21 A. Nothing, zero. I had one -- I had one
22 interview with him up in Chester or something like
23 that.

24 Q. What was the interview about?

25 A. I wanted to see what his credentials

1 were. I wanted to see if he knew what he was
2 talking about.

3 Q. Well, when he says on May 14 that he
4 requested some further information --

5 A. I don't know what -- the information I
6 am sure had to do with the scope of his review as
7 opposed to our review.

8 Q. And then he says "and generally
9 reviewed what the expert report will be speaking
10 to." What do you mean?

11 A. Right. In other words, I know
12 exactly. That would -- would take -- I knew nothing
13 about the technology of tableting. I didn't want to
14 offer an opinion at all, zero, I didn't even want to
15 touch it.

16 Q. And did you?

17 A. No, of course not.

18 Q. Okay.

19 A. But he was. I wanted to make sure
20 that he's covering that and I'm covering this. And
21 I don't want him delving in an area that he's not an
22 expert in, okay.

23 Q. And so when Russell Somma --

24 A. So we tried -- we tried to set up a
25 line.

1 Q. So when Russell Somma says to you on
2 this is May 12, I think I said May 14th. It's May
3 12, 2010. We need to coordinate our efforts?

4 A. Yes, that's it.

5 Q. What does that mean to you?

6 A. It meant using a vin (phonetic)
7 diagram, who's covering what.

8 Q. And what did you decide?

9 A. We decided that he covers anything to
10 do with tableting and we would cover everything
11 else.

12 Q. Is Denise your wife?

13 A. Yes, she is.

14 Q. And on April 26, 2010, I see an e-mail
15 here from SpyGlass Group to Meghan Johnson Carter,
16 Re SpyGlass billing, as follows: "Hi, Meghan, this
17 is to confirm 340 per her for Russ and 430 per hour
18 for SpyGlass."

19 A. Correct.

20 Q. What does that mean?

21 A. That means originally when we talked
22 to Motley, we -- we did it under the understanding
23 that he would be part of our consulting group. Much
24 like all other consulting groups, you bring in
25 experts as is necessary. I had a discussion with

1 him, and I was feeling more and more uncomfortable
2 about the scenario, so -- but I explained to him, I
3 said there is a loss on our part if you feel that
4 Russ can do the work. So we negotiated an
5 additional \$30 per. So Russ would do his own thing
6 and we would do our own thing. So we increased our
7 hourly rate \$30.

8 Q. Sounds like Russ was part of the
9 group?

10 A. Russ was not part of the group.
11 That's the reason why we got -- we did the split
12 that way. He was not part of the group. He never
13 billed. He's not part of our group in any manner,
14 there is no contract, there's not even an implicit
15 contract, nothing.

16 Q. Why -- why do you think your wife told
17 Meghan what his hourly rate was?

18 A. Because -- because originally, the
19 concept was that he would be part of the SpyGlass
20 Group.

21 Q. Well, this is April 26, 2010.

22 A. I don't care what date -- the date is
23 immaterial to me. I am explaining to you what the
24 arrangements were.

25 Q. Your initial draft report was

1 January 1, 2010.

2 A. It doesn't -- okay.

3 Q. Right?

4 A. If it is, yeah, I gave you the report.

5 Q. I'll guarantee it is, and it's right
6 in front of you.

7 A. Oh, no, no. This is not January 2010.
8 This is a place keeper. This has nothing to do with
9 anything.

10 Q. So you're looking at your initial
11 draft report, and it's dated January 1, 2010?

12 A. It's meaningless. That's a place
13 keeper.

14 Q. What do you mean by that?

15 A. I put January -- a place keeper, it's
16 so that I don't forget to put a date. It's not the
17 date of the report, has nothing to do with --

18 Q. What is the date of the report?

19 A. I don't know. You'd have to -- I
20 don't know what the date of the report is.

21 Q. Well, look at it and tell me.

22 A. I can't -- unless I wrote it down, I
23 can't tell you.

24 Q. Okay. I -- the only thing I see in
25 writing on your draft report is January 1, 2010.

1 You see that?

2 A. Now I understand some of the lack of
3 understanding.

4 Q. Do you see January 1 --

5 A. I could have put -- I could have put
6 January 1949. It's meaningless. This is a place
7 keeper.

8 Q. Okay. On your -- on your draft report
9 that you have in your hand right now --

10 A. On every report, I don't put the date
11 until I was ready in the June whatever time frame.
12 That's -- that's when I started dating it because it
13 started making sense to date it.

14 Q. Did you start dating it January 1,
15 2010 after January 1, 2010?

16 A. You're going to have to ask that
17 again, please.

18 Q. Let's go back. I'm trying to figure
19 out here why it is in April 26 -- on April 26, 2010,
20 your wife, who does the business end of the SpyGlass
21 deal, writes to Meghan saying Russ' rate is 340 an
22 hour. And all I'm trying to do is establish that
23 looks like Russ was part of the collaborative effort
24 that went into this report?

25 A. That couldn't be more -- that couldn't

1 be more false.

2 Q. Okay. And I'm also looking at your
3 draft report, and you look at it too, and you tell
4 the jury what date is on there?

5 A. It says January 2010, but it is a --

6 Q. Just a minute. What date is shown on
7 that report?

8 A. Excuse me, sir. January 1st, 2010.

9 Q. All right. That's my -- that' all I
10 want you to --

11 A. Okay.

12 Q. I see another e-mail among the
13 documents that you gave me here from Sal Romano to
14 Meghan Johnson Carter with copies to Sandy Summers.
15 Who is that?

16 A. I don't recall.

17 Q. Fred Thompson, you know Mr. Thompson
18 from Motley, right?

19 A. Well, I talked to him on the phone
20 once.

21 Q. And the subject is, "need some files."
22 Sal says: March 17, 2010: "Meg, I think we had a
23 good meeting with you and Pete Miller on the phone
24 on Monday. We have a better idea of what you want
25 from us, and we believe we can deliver it to you to

1 your satisfaction."

2 A. In other words, a complete report.

3 Q. What "better idea" did you get of what
4 they, the Plaintiff's lawyers, wanted from you?

5 A. I -- I don't know that I can answer
6 that. I don't recall.

7 Q. What is it that you could deliver to
8 the Plaintiff's lawyers to their satisfaction?

9 A. A comprehensive report because without
10 some direction, having no experience, zero, in this,
11 you know, you're dealing in somewhat of a void.

12 Q. So you relied upon the plaintiff's
13 lawyers to tell you what they wanted in your report?

14 A. What their -- what the objective was.
15 What is the objective, which later appeared in my
16 report.

17 Q. When was it that you were first
18 contacted by the plaintiff's lawyers?

19 A. I don't have the date, but the e-mail
20 trail would -- would speak to that.

21 Q. How much have you billed the
22 plaintiff's lawyers to date for the work that you
23 have done?

24 A. Approximately \$90,000.

25 Q. And how about Sal Romano?

1 A. I'm going to guess, I don't know
2 exactly, but I'm going to guess 20,000.

3 Q. And how much time do you have that is
4 yet unbilled?

5 A. How much time, 14 yesterday, four and
6 a half, and today.

7 Q. That's it?

8 A. That's it.

9 Q. Everything else has been billed?

10 A. Everything else is billed, paid in
11 full.

12 Q. So you billed approximately 90,000 or
13 exactly 90,000 or 100,000?

14 A. Within -- I have the numbers over
15 there, but it's 90,000. I have the records for you.

16 Q. Okay. Well, we'll get to that.
17 You -- you and Sal agreed that the batch records
18 would be critical for you to review?

19 A. We wanted to see a lot of records,
20 correct.

21 Q. You and Sal agreed that the batch
22 records would be critical for you to review,
23 correct?

24 A. Yes.

25 Q. 152 batches were recalled; is that

1 right?

2 A. I'd have to look at the numbers.

3 Q. Is that approximately, correct?

4 A. I'm going to assume that it is, it was
5 a lot -- lots.

6 Q. You only looked at three batch
7 records, didn't you?

8 A. Those were the only ones that I had
9 available, the only ones that were part of the data
10 base. You know, you get what you get. There was a
11 lot of information everybody wants.

12 MR. KAPLAN: I'm going to mark this as
13 Exhibit 112.

14 (Whereupon, Exhibit 112, E-mail, was
15 marked for identification as of today's
16 date.)

17 BY MR. KAPLAN:

18 Q. I'm handing you Exhibit 112. First,
19 look at the e-mail from Sal Romano to you dated
20 February 24 -- I mean from you to Sal, dated
21 February 24, 2010. You say as follows: "Sal, the
22 actual batch records are extremely important. Do
23 you want me to request the information? Mark."
24 Then above that is an e-mail from Sal dated
25 February 24 to Meghan Johnson Carter saying, "Mark

1 and I believe the batch records will be critical for
2 us to review."

3 Do you see that?

4 A. Yes.

5 Q. "How many batches are recalled? Do
6 you have all the batch records as PDF files? We
7 have lots to read now, but I think we'll have to
8 look at the batch records soon, right?"

9 A. Yes, that's what it says.

10 Q. Did you?

11 A. Did I see additional batch records
12 other than those that I have either here or in the
13 references, no.

14 Q. You looked at only three batch
15 records?

16 A. Three -- I believe that's correct,
17 three or four.

18 Q. You looked at three batch records,
19 didn't you?

20 A. I would have to add them up, but it's
21 at least three. Yeah, but let's say three.

22 Q. That was your sworn testimony on June
23 29, 2010. Are you changing that testimony?

24 A. No, I'm not.

25 Q. All right. You looked at three batch

1 records.

2 A. Okay.

3 Q. Meghan told you that there are
4 approximately 170 plus batches for Digoxin, right?

5 A. Yes.

6 Q. And you looked at three?

7 A. I looked at three.

8 Q. But they were critical?

9 A. They were critical if you wanted to
10 find more exceptions, more issues.

11 Q. Doesn't say if we wanted to find more
12 issues. You say they're critical.

13 A. That's what I said, and I'm telling
14 you what that means.

15 Q. And you stand by that, don't you?

16 A. What do I stand by, that I wrote that?

17 Q. Those are your words, aren't they?

18 A. I wrote that in an e-mail, that is
19 correct.

20 Q. Those are your words, are they not?

21 A. Those are my words.

22 Q. There were a number of phone
23 conferences with Russell Somma, weren't there?

24 A. We talked a couple of times. I don't
25 know the number.

1 Q. Well, I'm looking at another e-mail
2 here dated March 30, 2010 from Russell Somma to you,
3 to Meghan Johnson Carter, to Pete Miller, and to Sal
4 Romano with a copy to Sandy Summers saying, "Mark,
5 Meghan, Sal, and Pete, I will be available for a
6 telephone conference on Monday at 9 a.m. and hope
7 this accommodates everyone's schedule. Sorry about
8 the delay as I'm traveling right now."

9 A. Okay.

10 Q. Does that refresh your recollection
11 that --

12 A. I don't remember that meeting actually
13 being held, but I'm going to assume it probably was.
14 It was an unmemorable meeting.

15 Q. Now, Russell Somma has a bachelor of
16 science in pharmacy, doesn't he?

17 A. If his résumé says that.

18 Q. And a masters in science and
19 pharmaceutical science?

20 A. If his resume says that.

21 Q. And a PhD in pharmaceutical science?

22 A. If his resume says that.

23 Q. So you -- you had no idea what his
24 qualifications were?

25 A. I read that and I received

1 recommendation that he knew -- his expertise, and
2 therefore, I wanted to interview him to see how
3 practical, was he a theoretician or did he know what
4 he was talking about.

5 Q. Did he disagree with the conclusions
6 that you came to?

7 A. He never saw any conclusions that I
8 came to, not a single piece of paper.

9 Q. Never heard you say what your
10 conclusions were?

11 A. No, he did not.

12 Q. How about Sal's conclusions?

13 A. You have to talk to Sal, but I don't
14 believe that he talked to Sal outside of
15 conversations that we had. I'm almost positive.

16 Q. Who is Denise DeLongas?

17 A. That's my wife.

18 Q. Oh, okay. Sorry.

19 A. Wonderful lady.

20 Q. I'm sure.

21 A. Best of the best. Can you put that
22 down in the record?

23 Q. You just did.

24 A. Excellent.

25 Q. You just did, and you know what, it

1 was Valentine's day Monday, but I think you ought to
2 show it to her now and --

3 A. We don't go there.

4 Q. Okay. On March 23, 2010, you sent an
5 e-mail to Meghan Johnson Carter with copies to Fred
6 Thompson and Pete Miller saying that you would like
7 them to review Russ Somma's qualifications. And you
8 said, "I recommend you consider Russ Somma as part
9 of the evaluation team."

10 A. Right.

11 Q. "Russ has worked very closely with one
12 of the SpyGlass Group's core members. His
13 credentials are outstanding."

14 A. Right.

15 Q. That's what you -- that's what you
16 told the plaintiff's lawyers, and that's what you
17 recommended?

18 A. Yes. That's correct. But his
19 credentials means Bob Sierra's credentials.

20 Q. Whose credentials?

21 A. Bob Serra, the gentleman that I talked
22 to about finding an expert. He said that this --
23 that this guy's the best. I said great. Let's
24 talk.

25 Q. And you recommended him?

1 A. I recommended that they consider him,
2 that's what I said. I can't -- I didn't recommend
3 him because I never worked with him, but I talked to
4 him, he's a bright guy. He's got great experience,
5 he knows his stuff.

6 Q. He worked with somebody in the
7 SpyGlass Group?

8 A. Bob Serra, apparently they have a long
9 term relationship. I never heard the man's name
10 before, nor did Sal.

11 Q. As late as June 4, 2010, you and Sal
12 were meeting with the Plaintiff's lawyers?

13 A. Were meeting what?

14 Q. With the Plaintiff's lawyers?

15 A. The Plaintiff's lawyers? On the
16 phone, we probably discussed things.

17 Q. How about early Friday morning,
18 June 4th, at the Newark airport?

19 A. We met.

20 Q. That wasn't on the phone, that was in
21 person?

22 A. That was in person, correct.

23 Q. You -- you met in a hotel conference
24 room there?

25 A. Yes.

1 Q. Did you forget that?

2 A. Yes.

3 Q. And you met to discuss the report?

4 A. That's correct.

5 Q. Which Sal told Meghan Johnson Carter
6 on May 28 was in good shape?

7 A. Okay.

8 Q. And it's in its fourth draft; is that
9 right?

10 A. If that's what it says.

11 Q. He says we. Doesn't say Mark.

12 A. That's correct. He was proofing it.

13 Q. He says, "We are planning to have it
14 done next week."

15 A. That's correct. If it says that, that
16 is correct.

17 Q. Sounds like he's had a lot of input on
18 this report?

19 A. He's had no input to the context --
20 content of that report. None.

21 Q. Well, what was he billing all of that
22 time for?

23 A. His review time. It was redundant.

24 Q. So you're saying Sal Romano is
25 redundant?

1 A. I'm saying some of the work he looked
2 at and the work he did was redundant.

3 Q. So when -- when Sal Romano says on
4 May 24, 2010 in an e-mail to Meghan Johnson Carter,
5 "Meg, let's talk about strategy for a moment."

6 A. I'm sorry. You have to repeat that.
7 Can I read these?

8 Q. Just -- just try to answer my
9 questions, okay. So when -- so when Sal Romano says
10 to Meghan Johnson Carter on May 24, 2010, "Meg,
11 let's talk about strategy for a moment." And goes
12 on to say, "Mark and I will both sign our SpyGlass
13 report."

14 A. Right. That was originally the
15 concept.

16 Q. Well, it was the concept through the
17 meeting at the Newark airport hotel conference room
18 on June 4, 2010?

19 A. Okay.

20 Q. Eleven days later, you submitted the
21 report?

22 A. Right.

23 Q. You had had a prior meeting, a meeting
24 prior to May 24, 2010 with the plaintiff's lawyers,
25 didn't you?

1 A. A meeting where? We talked on the
2 phone a few times.

3 Q. Sal goes on to say in this e-mail of
4 May 24, 2010 to Meghan Johnson Carter, "So if I
5 understood you at our meeting with Pete, you will
6 want to depose both Mark and me."

7 A. Right. We met with them twice, one in
8 New York City, one in Newark, and you're referring
9 to both of those meetings. On and off he referred
10 to them.

11 Q. He goes on to say on May 24, 2010,
12 "Then should we be doing this on the same day? If
13 that is the case, then I can't make it on June 24 or
14 25. I do have free time June 16 and 23. I don't
15 know about Mark." The plan was that Sal was going
16 to sign this report along with you?

17 A. That's correct.

18 Q. And that Sal was going to be deposed
19 as an expert as well?

20 A. I assume that is correct. Well, it
21 depends --

22 Q. What -- what changed that plan?

23 A. He couldn't -- he couldn't do it. He
24 didn't have the -- his schedule would not allow it.

25 Q. What?

1 A. His schedule would not allow it.

2 Q. Well, he says -- he gives dates when
3 he is available.

4 A. Whatever. I don't know. He talked, I
5 assume with them, and the dates, including science
6 day, including some trial date. There is no way he
7 could possibly make it, so he felt that he couldn't
8 be -- participate any further.

9 Q. I do have free time, he says, June 16
10 and 23. That's what he says?

11 A. I go by what I just said, he cannot
12 give a full commitment, as I could. I can give a
13 full commitment.

14 Q. So let me understand this now. Sal
15 Romano contributed to the report and to the opinions
16 that were expressed in that report, but he was
17 pulled off to avoid his deposition?

18 A. That is not correct. That report is
19 my report. Okay. Every bit of it is my report.
20 Sal acted as a consultant to me of which I was the
21 one with the experience, not Sal.

22 Q. Sal, in another e-mail, says, "It was
23 a pleasure meeting" -- to Meg, "It was a pleasure
24 meeting you and Pete in NYC."

25 A. Yeah.

1 Q. That was a meeting in the city?

2 A. Right.

3 Q. "I'm available pretty much from
4 June 16 to 23 for a deposition if they want me."

5 A. Right. But he couldn't commit beyond
6 that, and his fear was that he would have to
7 interrupt all of his business and personal plans to
8 continue this -- this project.

9 Q. You said something about -- well, he
10 also says, "I will be available for the trial dates
11 if needed."

12 A. I can't tell you what that says. I
13 can tell you that he felt he could not commit to the
14 time and bowed out. It could say whatever it says,
15 I don't know.

16 Q. Well, these aren't my words, these are
17 Sal Romano's words.

18 A. You have to talk to Sal as to why he
19 felt he could not do it.

20 Q. And that's what I'm wondering, how in
21 the world am I going to be talking to Sal when he
22 apparently has a role in the report that was
23 rendered on June 15 --

24 MS. CARTER: Objection.

25

1 BY MR. KAPLAN:

2 Q. -- 2010 but didn't sign that report?

3 A. It sounds like a rhetorical question.
4 I don't understand your question.

5 Q. What don't you understand?

6 A. Well, I didn't -- it sounds like you
7 made a question and then answered it.

8 Q. I'd love to hear what Sal Romano has
9 to say, but he was pulled off the report, wasn't he?

10 A. He pulled himself off of it because of
11 a commitment.

12 Q. When was the last time you talked to
13 Sal Romano about the report?

14 A. The report? It was before it was
15 issued. I didn't talk to him since about this
16 subject. I've talked to him, but not about this.
17 He had no interest in it.

18 Q. Okay. Number four, all documents
19 including documents and deposition transcripts which
20 refer or relate to DIGITEK that the witness received
21 from any source. You brought all of that?

22 A. Yes.

23 Q. Where is it?

24 A. You -- you have everything.

25 Q. Where?

1 A. Read it again, just to make sure.

2 Q. All documents including documents and
3 deposition transcripts which refer or relate to
4 DIGITEK that the witness received from any source?

5 A. Deposition? I received nothing.

6 Q. No, no. You're focusing on
7 depositions.

8 A. I need to read that, sir.

9 MR. KAPLAN: Okay. Can you put that
10 in front of him, Meghan?

11 (Off-the-record discussion.)

12 Here you are. We'll just mark this as
13 Exhibit 113.

14 (Whereupon, Exhibit 113, Amended
15 notice for video deposition, was marked for
16 identification as of today's date.)

17 BY MR. KAPLAN:

18 Q. Just for the record, Exhibit 113 that
19 I've put in front of you is the document that we've
20 been talking about which is the amended notice for
21 your video deposition here today requesting that you
22 bring categories of documents that are listed. You
23 understand that, right?

24 A. Oh, certainly.

25 Q. And you saw it before you came here

1 today?

2 A. Yes, I did.

3 Q. And you have complied with the
4 request?

5 A. That's correct.

6 Q. And we're going through to make sure
7 now that -- that you did and that I have everything
8 and that Mr. Anderton has everything. Okay?

9 A. Yes.

10 Q. All right. So we're at number four.
11 All documents including documents and deposition
12 transcripts which refer or relate to DIGITEK that
13 the witness received from any source.

14 A. The only depositions I have are the
15 ones that we've talked about, and I have my own
16 deposition. That's it.

17 Q. Again, with all due respect, as I said
18 before, you're focusing on the word deposition.
19 Look before that. All documents including --

20 A. This is -- this is everything that is
21 here falls underneath that. There is --

22 Q. So when you say "everything that is
23 here," and you point to something on the ground?

24 A. I point to three huge volumes of paper
25 that I've collected and kept together so that when

1 this is asked, I can hand it over.

2 Q. That's fine. And I just -- all I want
3 to do is have that.

4 A. Yes. You have it all. You started
5 looking at it, sir. I'm sorry. I'm not trying to
6 be argumentative.

7 Q. With -- with -- with all due respect,
8 I'm just trying to identify what is responsive to
9 these requests.

10 A. I understand. I think that's fair.

11 Q. All right. Thank you. And so I want
12 to mark all of the documents that you pointed to
13 over there that you say are crates or whatever. I
14 know you -- I know you came up with some --

15 A. Crates is a better word.

16 Q. Okay. Notebooks. So we can mark
17 those now. Let's -- let's just do that.

18 MR. KAPLAN: In fact, we can take a
19 break and -- and we'll mark them. We'll
20 just take a minute or two. I just want to
21 make sure we have those marked, they are
22 part of the record.

23 THE VIDEOGRAPHER: We're off the
24 record. The time is 2:19.

25 (recess taken.)

1 (Whereupon, Exhibits 114-139,
2 documents brought by the Witness in three
3 milk crates, were marked for identification
4 as of today's date.)

5 THE VIDEOGRAPHER: We're back on the
6 record. The time is 2:35.

7 BY MR. KAPLAN:

8 Q. We went off the record so that we
9 could mark as exhibits the documents that you
10 brought with you here today. The court reporter has
11 marked those documents as exhibits 114 through 139.
12 Does that include everything that you brought with
13 you?

14 A. Yes.

15 Q. All right. And we're going through
16 the list of documents that you were requested to
17 bring pursuant to the amended notice duces tecum for
18 your deposition. We were on number four, all
19 documents including documents and deposition
20 transcripts which refer or relate to DIGITEK that
21 the witness received from any source. And those
22 documents are among exhibits 114 through 139, right?

23 A. All of them are among that, yes.

24 Q. Okay. Number 5 asks for all retainer
25 agreements or other agreements under which the

1 witness has been or will be paid for work related to
2 the DIGITEK litigation?

3 A. Okay. This is a portion of it.
4 There's another folder in there. Let me give you a
5 portion of it. Here it is. Here are all of this
6 (handing). That -- that's going to be duplicates,
7 by the way. This should have everything.

8 Q. By the way, when your deposition was
9 taken on June 29, 2010, you said that 50 percent of
10 the work that you were doing was for the plaintiff's
11 lawyers in this litigation, 50 percent of your total
12 work?

13 A. Perhaps at that period of time. It's
14 not -- it is approximately about over 30, less than
15 40 percent. Because I grossed almost \$400,000, so
16 90, at that point, would be 25, so it's less. But I
17 was getting paid more and more by the end of the
18 year. I did a lot of assignments.

19 Q. So you're saying in 2010, you grossed
20 \$400,000?

21 A. Almost, 380,000.

22 Q. And that your total bills to the
23 plaintiff's lawyers were?

24 A. Approximately 90.

25 Q. So about 25 percent of your income?

1 A. Yeah. Right.

2 Q. In 2010 --

3 A. Correct.

4 Q. -- was attributable to work that you
5 did for the Plaintiff's lawyers in this litigation?

6 A. That's correct.

7 Q. But you -- you made a distinction in
8 your previous deposition as to the percentage of
9 your income and the amount of your work related to
10 this litigation. You said 50 percent of your work
11 was related to the DIGITEK litigation?

12 A. I believe you talked to me up to that
13 point, you said up to that point. Then I said, well
14 I have all of these promissory notes, I'm going to
15 get contracts, I've got to get paid another 40,000,
16 and you said no, up to that point. And that's what
17 I answered.

18 Q. Okay. Up to June 29, 2010?

19 A. Yes, that was my guess. But I also
20 told you I didn't know, and I don't pay attention to
21 it.

22 Q. Got you. I do note here on this
23 notebook that you gave me which has been marked as
24 Exhibit 135 which has the label "DIGITEK Motley Rice
25 attorneys at law." Is that from your shop, from

1 your -- from SpyGlass?

2 A. No. That's information I received
3 from -- probably I received from Motley. I had
4 asked for some copies --

5 Q. Who made this notebook?

6 A. That was made, I believe -- let me
7 double check and make sure.

8 Q. Is this -- is this a Spyglass notebook
9 with your --

10 A. Let me just see it. I'll tell you by
11 the labeling and whatnot. This is a SpyGlass
12 notebook. My wife did this.

13 Q. Okay. All right. And the label on
14 the front?

15 A. Yeah.

16 Q. And the handwriting on the front is
17 yours, right?

18 A. That handwriting is mine.

19 Q. It says "MK," Mark Kenny, right?

20 A. Yes.

21 Q. Legal requirements?

22 A. Yeah. That meant that this section of
23 the -- of the request for the documents I think is
24 Number 5. I tried to put anything that was legally
25 or financially related in there.

1 Q. Okay. The first page in this notebook
2 marked Exhibit 135 is a note from your wife, Denise,
3 to Meghan Johnson Carter, a message dated -- faxed
4 on May 15, 2010, one month before you submitted your
5 report saying, "Hi, Meghan, time sheets for Mark
6 Kenny and Sal Romano, thanks DD."

7 A. Right. That's my wife.

8 Q. Okay. That's the same Sal Romano
9 we've been talking about?

10 A. Yes.

11 Q. The proofreader?

12 A. The proofreader.

13 Q. I don't see anything -- the latest
14 invoice I see is August 24, 2010. I don't see
15 anything more current than that. Can you help me?

16 A. No, that should be it.

17 Q. August 24, 2010?

18 A. Yeah, I didn't do any work.

19 Q. So -- so you haven't billed for any
20 work since August 24, 2010; is that right?

21 A. That is correct. If those are the
22 records there. That is a complete set of records.

23 Q. I notice that one of the invoices
24 you've produced here, invoice statement number 1032,
25 which was invoiced on June 21, 2010, describes the

1 services as consulting experts exhibit review and
2 deposition writing, Sal Romano time sheet,
3 5/11-6/15?

4 A. Uh-huh.

5 Q. So Mr. Romano was working with you on
6 the report up until you submitted it on June 15?

7 A. Yes. Well, he was up to some point.
8 I don't know, a week or so before, perhaps.

9 Q. And this is for 26 hours of
10 Mr. Romano's time?

11 A. Right.

12 Q. To proofread?

13 A. To proofread, and he probably tried to
14 do some research. I don't know.

15 Q. Twenty-six hours at \$430 an hour,
16 total, \$11,180?

17 A. Yes.

18 Q. And here's an invoice dated May 11,
19 2010 showing Sal Romano time sheets 2/26 to
20 4/2/2010, 14 and a quarter hours, and time sheets
21 from 4/7 to 5/10, 32 hours. For a total of 18 --
22 \$19,460 for his time?

23 A. Okay.

24 Q. Well, you tell me, if I just add those
25 two together, 19,000 and 11,000, there's 30,000 for

1 Sal Romano, not 20,000?

2 A. It could be anything, I don't -- I
3 have nothing to do with billing. I have nothing to
4 do with those numbers. Sal puts them in and gives
5 then to Denise.

6 Q. And that's -- that's all before the
7 \$19,460 between February 26 and May 10. Is that
8 before the first draft of the report?

9 A. Well, no. I started drafting the
10 tables. The tables, remember, I explained that
11 I did -- the tables were the beginning of the
12 report.

13 Q. I was just confused because the first
14 report I see is dated January 1, 2010, and you tell
15 me it says January 1, 2010, but it doesn't mean
16 January 1, 2010?

17 A. That is correct.

18 Q. And I'm still searching for the date
19 of the first draft?

20 A. I don't know what the date is.

21 Q. Did you tell the plaintiff's lawyers
22 that Mr. Romano was billing all of this money just
23 to proofread your report?

24 A. I didn't tell them anything.

25 Q. Did they have any expectation as to

1 what Mr. Romano's role --

2 A. The original expectation was that it
3 would be a co-authored report.

4 Q. And -- and would testify by way of
5 deposition as an expert witness?

6 A. That was the initial expectation.

7 Q. So you've brought all of the bills
8 that you've sent?

9 A. Right.

10 Q. And you said that the only time
11 remaining is the time that you described earlier
12 which was two days before your original 2011
13 deposition was set?

14 A. Right.

15 Q. Where you spent one and a half days,
16 14 hours approximately, putting together all of
17 these documents?

18 A. Correct.

19 Q. You want to make sure we don't lose,
20 and I understand that.

21 A. Correct.

22 Q. And then an additional two hours and
23 then eight hours to review and reread all of the
24 referenced documents, and then another four hours
25 with Meghan yesterday, and then the time today?

1 A. Yes.

2 Q. So you have somewhere between 30 and
3 40 more hours to bill?

4 A. You mean including deposition, et
5 cetera?

6 Q. Yes.

7 A. If the numbers come out to that.

8 Q. So somewhere between 12 and 16,000
9 more.

10 A. Okay.

11 Q. So that will push you over 100,000?

12 A. Are we talking about -- for Motley,
13 that's correct.

14 Q. For Motley as opposed to?

15 A. As opposed to my other income.

16 Q. Oh, yeah. Okay. But that will push
17 you over \$100,000 for your work as an expert witness
18 in this case?

19 A. That's correct.

20 Q. And your work as an expert in this
21 case, did you do anything other than review
22 documents?

23 A. Can you give me an example? No, no.

24 Q. Did you do anything other than review
25 documents?

1 A. No, not that I'm aware of, not that I
2 can think of.

3 Q. All you did as an expert witness was
4 review documents?

5 A. Yes.

6 Q. Documents that were sent to you by the
7 Plaintiff's lawyers?

8 A. Documents that were either sent to me
9 or were available on the Internet from Crivella
10 West.

11 Q. You did no original work yourself?

12 A. What does that mean?

13 Q. I don't know. Did you do any
14 independent work.

15 A. No.

16 Q. In all of the documents that you
17 reviewed, you never saw any conclusion by the FDA
18 that Mylan was not in full compliance with FDA
19 regulations at all times as a wholesale distributor
20 of DIGITEK, did you?

21 A. I'm sorry. Let me reread that. What
22 number is that? Oh, this is a separate question?
23 I'm sorry. I thought you were reading from here.

24 MR. KAPLAN: Let me ask the court
25 reporter to repeat the question.

1 (Record read.)

2 A. That is correct. I did not see
3 Mylan's name.

4 Q. Category seven was the witness' entire
5 file including all electronic documents and
6 correspondence in connection with this matter. And
7 I think that's among the documents that you've
8 produced including the disks, right?

9 A. Correct.

10 Q. Number eight calls for documents that
11 you received or additional materials since June 29,
12 data or writings that you've reviewed or relied
13 upon, et cetera, in preparing reports in this
14 matter. And I think we've got all of that, don't
15 we?

16 A. Correct.

17 Q. Everything -- number nine is
18 everything the witness reviewed that indicates that
19 Plaintiffs suggested effective DIGITEK.

20 A. I saw nothing.

21 Q. So you have no opinions on that?

22 A. Absolutely none. I have no interest
23 in it.

24 Q. Okay. And ten is all notes that the
25 witness has taken in connection with review of this

1 matter?

2 A. I don't take notes.

3 Q. Other than on the documents?

4 A. I make the a lot of notes on there.

5 Q. Occasionally?

6 A. More than occasionally. You saw my
7 number of.

8 Q. But you don't have a separate set of
9 notes chronicling your review of documents?

10 A. No, absolutely not.

11 Q. All documents that the witness has
12 prepared concerning the subject matter of this
13 litigation, that's number 11. Are there any
14 documents that you've prepared other than reports or
15 correspondence?

16 A. Nothing.

17 Q. And you've brought all reports, draft
18 reports, that you've prepared?

19 A. Correct.

20 Q. At the last deposition, you had your
21 final report of June 15, and one draft report, the
22 one that's in front of you, which appeared to me
23 because I see it on there, to be dated January 1,
24 2010, right?

25 A. My apologies.

1 Q. At the last deposition, the only
2 reports you had were the draft report in front of
3 you that shows a date of January 1, 2010 and the
4 final report of June 15?

5 A. Right. And then I went back into
6 electronic records.

7 Q. And -- and today, you've brought some
8 additional drafts, right?

9 A. Correct.

10 Q. And we'll go over those. Okay.
11 Number 12, all medical, scientific, or other
12 literature upon which the witness relies in
13 connection with the opinions expressed in the
14 reports. Is there any medical, scientific, or other
15 literature upon which you are relying?

16 A. No, not for this report.

17 Q. That covers those documents. Okay.
18 Now, let's turn to some other matters.

19 I think you told me, I think this was
20 kind of off the record, but that your process for
21 arriving at your opinions were to construct a time
22 line; is that right?

23 A. That's correct.

24 Q. And then prepare tables?

25 A. Yeah, the tables that are attached to

1 the referenced documents.

2 Q. When -- when you say "tables attached
3 to the referenced documents," can you be more
4 precise in explaining what that is?

5 A. Well, the table is the referenced --
6 the attachments.

7 Q. Oh, the attachments to your report?

8 A. Yes.

9 Q. Okay. So you started by creating the
10 time line, and we earlier looked at a time line?

11 A. Correct.

12 Q. To give you a sense of the chronology,
13 right?

14 A. Of space, yes.

15 Q. And then -- and then that helps you
16 then prepare these tables that are attached as
17 appendices to your report; is that right?

18 A. That is correct.

19 Q. So from that information, then, you
20 constructed a rough draft of a report?

21 A. Correct.

22 Q. And then you went from there to revise
23 it?

24 A. Correct.

25 Q. Okay. Your role as an expert witness

1 in this case was to determine whether or not Actavis
2 was in compliance with GMPs over the period 2004 to
3 2009, and to determine whether or not Actavis
4 released products that were violative of GMPs; is
5 that right?

6 A. That is correct.

7 Q. Okay. Take a look at the draft report
8 which is in front of you. Do you have that?

9 A. Yes.

10 Q. Who drafted that report and when?

11 A. I drafted it. I don't know the date
12 of it.

13 Q. What is the date that appears on the
14 document?

15 A. It says January 1st, but it is not
16 January 1st. That's a place keeper.

17 Q. It says January 1st, 2010, right?

18 A. Yes.

19 Q. I just honestly don't understand what
20 you mean when you say it wasn't January 1st, 2010,
21 it was just a place keeper. What does that mean?

22 A. It's just when I started formatting
23 the document, I said, well, it's got to have a date,
24 and it will be ultimately the date of the report.
25 So I just kept it as January 1st until I knew when I

1 was going to issue the report.

2 Q. Did you do this before or after
3 January 1st, 2010?

4 A. I have to look at my time line.

5 Q. You're now looking -- you've asked for
6 and you're looking at Exhibit, for the record, 135?

7 MS. CARTER: 135.

8 BY MR. KAPLAN:

9 Q. Which are your invoices; is that
10 right?

11 A. Yes. It looks like on or about -- I
12 started making some chronology around March.

13 Q. March of 2010?

14 A. Yes.

15 Q. And this is the first version of the
16 report; is that right?

17 A. That's correct.

18 Q. You have handwritten notes on this
19 report?

20 A. Yes.

21 Q. Does that reflect input that you
22 received from others?

23 A. It reflects a discussion I had with
24 Sal. He was across from me, we went through the
25 report. He read and we discussed, and then I made

1 notes.

2 Q. So this was something more than just
3 proofreading from Sal?

4 A. It was -- you mean -- describe what
5 you mean by proofreading.

6 Q. Well, you -- you told me before that
7 Sal's role was strictly to proofread and correct
8 spelling errors?

9 A. He looked at content and logic.

10 Q. So he had input then into the
11 substance of the report?

12 A. To a degree.

13 Q. And so did the Plaintiff's lawyers?

14 A. No.

15 Q. Did you share this draft with the
16 Plaintiff's lawyers?

17 A. No.

18 Q. All right. Look at the first page.
19 In other words, at this point in time, you did your
20 first draft and you kept it from the Plaintiff's
21 lawyers?

22 A. Correct.

23 Q. Why?

24 A. Because I didn't want to show it to
25 them. I didn't want to get any direction. This is

1 my report, not theirs.

2 Q. On the first page on the top
3 right-hand corner, it says "second discussion."
4 What does that mean?

5 A. That means Sal and I had talked about
6 this earlier.

7 Q. You also have a note on the first page
8 that says, "my experience," two exclamation points?

9 A. It just means -- I don't know what
10 that means, to be honest with you.

11 Q. Then you have a note that says simply?

12 A. "Sampling" -- wait a minute.

13 Q. "Sampling retained"?

14 A. "Sampling retained."

15 Q. What does that mean?

16 A. I don't know, I honestly don't.
17 Sampling retained? Could be two different notes.
18 Sampling could refer to the 100 percent inspection
19 sampling. Retained, did they look at retained
20 product. That's the only thing I can think of in
21 looking at that note.

22 Q. So, by time you compiled this draft
23 report, you had -- you had reviewed all of the
24 documents that had been sent to you?

25 A. You say sent to me. There was a

1 significant amount of information in Crivella West.
2 I tried to take all of the information that I had
3 time to review, and then I also reviewed the CD that
4 you have a copy of which is a duplicate of what's --

5 Q. Was there any documents -- were there
6 any documents or information that you didn't have at
7 the time that you prepared this first draft report,
8 which we should mark here as Exhibit 140. So we're
9 going to refer to this as 140. My question is: Was
10 there any -- were there any documents or information
11 that you didn't have that you needed to have in
12 order to fully express your opinions?

13 A. I don't recall. I would suspect that
14 since I was in the process of continually reading
15 documents that I saw other documents which could
16 have influenced the revision of this. So this was
17 not a complete -- perhaps complete at this point, I
18 don't recall.

19 (Whereupon, Exhibit 140, first draft
20 report, was marked for identification as of
21 today's date.)

22 Q. So you saw none one way or the other?

23 A. I don't know.

24 Q. Okay. Underneath "my experience,"
25 would you interpret your notes there for me, read

1 them.

2 A. That I should focus only on my own
3 experience, and I got to constantly go over this
4 based on my experience.

5 Q. Under that note, "my experience."
6 Only --

7 A. Oh, only reason recall because --

8 Q. Admit?

9 A. Admit by -- I don't know. I don't
10 know what it says anymore.

11 Q. Admit by end --

12 A. I don't know. I can't read my
13 handwriting.

14 Q. You can't read your handwriting?

15 A. No. I'm a lefty. You see what my
16 handwriting looks like.

17 Q. I understand. We all seem to be able
18 to interpret our own though.

19 A. Not in that case. I can't.

20 Q. You can't do it?

21 A. No, I can't.

22 Q. What would make sense to you there?

23 A. I can't -- I can't help you on that
24 one.

25 Q. Okay. So illegible even to the

1 author?

2 A. Correct.

3 Q. Okay. Then under that, there is a
4 question mark, and then it says once product sent
5 out?

6 A. I don't know what that meant, but it
7 meant something to me at the time.

8 Q. Look on Page 2. It says intro -- I
9 assume that Sal said you should have an
10 introduction?

11 A. Well, we discussed it. It wasn't that
12 Sal -- we discussed it.

13 Q. And concluded that there should be an
14 introduction?

15 A. Yes.

16 Q. And that the summary of the opinions
17 should be moved to the end?

18 A. Yes, it was kind of out of, you know
19 order.

20 Q. And then there is a note that says,
21 "make clear"?

22 A. Where is that? Oh, make clear -- I
23 don't know. Make something, format clear, summary
24 clear, I don't recall.

25 Q. But it was important to have a

1 one-page summary of your opinions, right?

2 A. It sounded like a good idea at the
3 time, yeah.

4 Q. Well, that's what you ended up with,
5 wasn't it, a one-page summary of your opinions?

6 A. I believe so, yeah.

7 Q. On Page 3, there's a note that says
8 "one first recalled, arrow double thick."

9 A. Right.

10 Q. What does that mean?

11 A. Just saying that the first recall was
12 only for double thick.

13 Q. And then two, you have written
14 "active." What does that mean?

15 A. I don't know.

16 Q. Read -- read your other notes here on
17 page three of your first draft report marked Exhibit
18 140.

19 A. Systems illustrate more of a systems
20 problem, treatment of evidence, looks like
21 treatment, not exhaustive list, just examples.
22 Forty-three reflects -- reflect fact findings.
23 There are four different investigations associated
24 with something but not by name.

25 Q. By the way, that first recall that you

1 noted about double thick, that was as to DIGITEK
2 only, wasn't it?

3 A. Yes.

4 Q. You have a note on the left-hand side
5 that says everybody will get asked about?

6 A. Every -- it's everything.

7 Q. Will get?

8 A. Will get asked about.

9 Q. What does that mean?

10 A. Meaning that you have to understand
11 what you're writing, make sure that you can
12 substantiate what you're writing.

13 Q. Did somebody have to tell you that?

14 A. Reinforce it perhaps, I don't know.

15 Q. Did Sal tell you that?

16 A. No, he did not tell me that.

17 Q. Did you tell yourself that?

18 A. I told myself that.

19 Q. Okay. Then on page 4, you have a
20 note, "qualify background," is that what that is?

21 A. Yeah. In other words, introduce
22 earlier what your background is and do a summary of
23 it. We had looked at some of the -- anyway, that's
24 what that means.

25 Q. Is that Sal's advice?

1 A. No, I don't think so.

2 Q. On page five, you have a note that
3 says, "In the body of this report, only the company
4 name Activas will be used." And then next to it,
5 "Done."

6 A. Yeah. What that means is I got up
7 front -- I -- I wanted to make sure that it was
8 clear that I was going to use the term Actavis and
9 not waffle back and forth depending upon the time
10 period, calling it Amide and then calling it Actavis
11 at a later time. So I wanted to make sure that I
12 defined in the introduction that when I referred to
13 Actavis, I referred to this organization which
14 originally was known as Amide.

15 Q. And then at the bottom on page five,
16 you have a handwritten note that says, "more detail
17 intro"?

18 A. Yeah.

19 Q. What's does that mean?

20 A. I assumed that we discussed it and
21 that the introduction didn't -- there was not enough
22 in the introduction and that -- helping organize it.

23 Q. The various other notes are made by
24 you. I'm going to try to get through this as
25 quickly as a result of your discussion with Sal

1 Romano, right?

2 A. Yes, or myself, or in reviewing it
3 myself.

4 Q. The draft report, if you look on page
5 28, has references listed, right?

6 A. Yes, the beginning of references.

7 Q. Now, nowhere in this draft report is
8 there any opinion with regard to Mylan, is there?

9 A. In this report?

10 Q. Well, let's look on Page 2, the
11 summary of your opinion. Is there anything in there
12 with regard to Mylan?

13 A. I don't see anything at this
14 particular revision level, no.

15 Q. So in Exhibit 40, there is no opinion
16 that you expressed as to Mylan?

17 A. At that particular point, that's
18 correct. I had not looked at the Mylan documents.
19 I only looked at the plaintiff documents and
20 whatever else is listed. There were probably more.

21 Q. On page 20 of your draft report,
22 Exhibit 140 that you're looking at, there is a
23 SpyGlass Group summary. Do you see that?

24 A. Yes.

25 Q. You wrote that?

1 A. Yes.

2 Q. You started off with, "Actavis
3 demonstrated a general incompetence in the handling
4 of this critical product quality." Right?

5 A. Yes.

6 Q. Then you go on, and you end with the
7 "Actavis environment was not focused on GMP and
8 quality systems."

9 A. Right.

10 Q. Not one word as to Mylan?

11 A. That's correct.

12 MR. KAPLAN: Let's let him change the
13 tape.

14 THE VIDEOGRAPHER: We're off the
15 record. The time is 3:11. This is the end
16 of tape 3.

17 (Recess taken.)

18 THE VIDEOGRAPHER: We are back on the
19 record. The time is 3:16. This is the
20 beginning of tape 4.

21 BY MR. KAPLAN:

22 Q. We're looking at your initial draft
23 report marked Exhibit 140 which shows on page 1 a
24 date of January 1, 2010?

25 A. Yes.

1 Q. We've gone through the report and
2 looked at notes that you have made, and you said
3 those were based on discussions you had with Sal
4 Romano?

5 A. Either by myself or with discussions
6 with Sal, yes.

7 Q. At least two discussions with Sal?

8 A. Two discussions with Sal, right.

9 Q. In fact, the notes from also based
10 upon discussions that you had with Meghan Carter and
11 Pete Miller as well?

12 A. I don't know. Could you explain where
13 they're at, I mean specifically?

14 Q. I'm asking you; is that right?

15 A. No, no, not at all.

16 Q. You are sure about that?

17 A. I'm positive about that.

18 Q. You sent a draft to Meghan and Pete,
19 didn't you?

20 A. No. I did not send a draft to Meghan
21 and Pete.

22 Q. Are you absolutely certain of that?

23 A. I'm certain of it, yes.

24 Q. And when you testified under oath on
25 June 29, 2010 and gave a deposition in this case and

1 gave sworn testimony, on Page 215, you were asked by
2 Mr. Moriarty: "To whom did you send this draft,"
3 your answer: "I sent it to Meghan, Sal, and Pete."

4 Question: "Was this a first draft?"

5 Answer: That was a first draft, the
6 draft that they saw, right."

7 Question: "And then in here, there is
8 handwriting. Is it your handwriting?"

9 Answer: "All of it is mine."

10 Question: "Is the handwriting based on
11 discussions you had with Plaintiff's counsel about
12 the draft."

13 Answer: "It is based upon two things or
14 three, if you will, one, listening to them;
15 secondly, coming up with ideas as I'm just going
16 through the document, and then later going back and
17 looking at it and making additional edits as I
18 reread it."

19 That was your sworn testimony on June 29,
20 2010, wasn't it?

21 A. If you said that then, that is my
22 sworn testimony, yes.

23 Q. You said it?

24 A. Yeah, I understand that.

25 Q. And today, you're telling a different

1 story?

2 A. Well, I guess I'm confused. The -- I
3 did have a meeting, I did send it. I didn't think
4 it was this particular revision, because it doesn't
5 look like any of the notes that -- I guess it is. I
6 don't know. I --

7 Q. You just swore under oath that you did
8 not send the initial draft to Pete and Meghan.
9 That's not true, is it?

10 A. I'd have to go back through my
11 e-mails.

12 MS. CARTER: Objection.

13 A. I -- I don't recall -- as of right
14 now, I don't recall sending this revision to Meghan
15 and Pete. I do not recall doing that.

16 BY MR. KAPLAN:

17 Q. Your sworn testimony when you were
18 deposed on June 29, 2010 was that you did send this
19 draft report to Meghan and Pete, wasn't it?

20 A. Yes.

21 Q. Are you telling the truth now or were
22 you telling the truth then?

23 A. To the best of my recollection right
24 now, I did not send it. I'd have to recreate
25 through e-mails, et cetera. I did send them a copy

1 at one point. I thought I recollected that was in
2 June.

3 Q. Let me show you that testimony that I
4 just quoted and see if there's any doubt in your
5 mind that you said on June 29, 2010 that you sent
6 this draft to Meghan and Pete.

7 A. June 29th?

8 Q. That's when you were deposed.

9 A. No, I understand that.

10 Q. I'm going to put in front of you your
11 sworn deposition testimony on June 29, 2010, and I
12 will refer you to Page 215 beginning at line 21 and
13 continuing through Page 216 line 17. Do you see it?

14 A. Just kind of point to it, if you
15 would.

16 Q. (Indicating.) I'm going to mark --
17 I'm going to mark these lines for you, and ask you
18 to read that testimony. You read that testimony.

19 A. Okay. Last document I'm holding
20 appears to be a draft for discussion purposes only.

21 Q. Start again, please, and read slower.

22 A. Question: "Okay. The last document
23 I'm holding here appears to be a draft for
24 discussion purposes only version of your report; is
25 that correct?

1 Correct.

2 To whom did you send this draft?

3 I sent it to Meghan, Sal, and Pete. Was
4 it the first draft? That was a first draft.

5 The first draft that they saw, right.

6 Right."

7 Q. That's not a question; that's your
8 statement, isn't it?

9 A. Yeah, I'm reaffirming it.

10 Q. The first draft that they saw, right.

11 A. "And then in here, there is
12 handwriting. Is it your handwriting.

13 All of it is mine.

14 Is the handwriting based on discussions
15 you had with Plaintiff's counsel about the draft?

16 It's based upon two things or three, if
17 you will, one, listening to them. Secondly, coming
18 up with ideas as I'm going through the document, and
19 then later going back and looking at and making
20 additional edits as I reread."

21 So, it looks like that my memory is
22 failing me right now that I did send this document
23 to them and discuss it.

24 Q. So when you denied sending the first
25 draft of the document to Meghan and Pete, that was

1 not the truth?

2 A. That was not accurate.

3 Q. And when you said that the Plaintiff's
4 lawyers, Pete Miller and Meghan Carter, had no input
5 into your report, that was inaccurate?

6 A. No. They had no substantive input
7 into the report. In other words, the data, the
8 conclusions. They couldn't because this is my
9 report, my thinking. I wouldn't allow anybody to
10 persuade me into saying something that was not true.

11 Q. In your report, this report that we're
12 referring to, Exhibit 140, says not one word about
13 Mylan?

14 A. That's correct.

15 Q. In fact, that report, Exhibit 140,
16 says, "In body of this report, only the company name
17 Actavis will be used." Correct?

18 A. That is referring to -- yes, that's
19 correct, it does say that.

20 Q. Somebody told you, gee, Mr. Kenny,
21 we've looked at your report here, your initial
22 draft, Exhibit 140, and you don't say anything about
23 Mylan. You better add something about Mylan.

24 A. I was asked a question, have you --
25 have you gone through the Mylan documents? I said I

1 have not gone through the Mylan documents.

2 Q. Who asked you that question?

3 A. I believe it was Pete Miller. He had
4 a question. And I said I have not gone through it.
5 And he says, well, do you have any opinion. I said
6 I have to read the Mylan document. I didn't even
7 open them up.

8 Q. At this point in time when you got to
9 the point of drafting an opinion that is 35 pages
10 long that you shared with your colleague, Sal
11 Romano, that you shared with Plaintiff's lawyers,
12 Pete Miller and Meghan Carter, you hadn't looked at
13 any Mylan documents?

14 A. I had not looked at any Mylan
15 documents at that point.

16 Q. Did you have any idea that Mylan was a
17 defendant in this lawsuit?

18 A. No, I actually did not. I didn't know
19 what their role was in terms of the legal situation.
20 I was asked to look at two -- initially asked to
21 look at different things which is in this report.
22 And they had questions, did I look at Mylan, and I
23 said no, I haven't looked at any information
24 regarding Mylan. And they directed me, it's under
25 Crivella West under so and so tab, et cetera, and I

1 went to -- I went to the tab, I started reading it.
2 And I made some conclusions off of the information
3 that I read, but that's the extent of the direction.

4 Q. In your 35 page draft report, Exhibit
5 140, you mention not one word about Mylan, and
6 others reviewed it and said you better express
7 opinions about Mylan because that's what we want?

8 MS. CARTER: Objection.

9 A. No, that's not even remotely close,
10 the way you put it. They asked me very specifically
11 have you had an opportunity to look at Mylan, and I
12 said no. They said the Mylan documents are in
13 Crivella West under dot, dot, dot, and -- anyway, so
14 then I took a look at them.

15 BY MR. KAPLAN:

16 Q. So now you remember a specific
17 conversation with the Plaintiff's lawyers in which
18 they asked you have you looked at the Mylan
19 documents?

20 A. I thought it was a later discussion.
21 Quite honestly, I thought it was later in perhaps
22 the discussion process.

23 Q. Until I confronted you with your sworn
24 testimony on pages 215 and 216 of your previous
25 deposition of June 29, 2010, you denied sending this

1 report to the plaintiff's lawyers?

2 MS. CARTER: Objection.

3 BY MR. KAPLAN:

4 Q. Correct?

5 A. It appears that is correct.

6 Q. Appears?

7 A. Yeah.

8 Q. It is incorrect? It is correct?

9 A. No, you're right. It is incorrect. I
10 misspoke. I didn't lie, I misspoke. You know, in
11 trying to put together the sequence, the chronology,
12 I misspoke.

13 Q. Let's look at the next draft of your
14 report.

15 (Whereupon, Exhibit 141, Draft of
16 expert opinion report, was marked for
17 identification as of today's date.)

18 BY MR. KAPLAN:

19 Q. I've put before you Exhibit 141 which
20 is a subsequent draft of your expert opinion report.
21 And I will say for the record, according to the disk
22 that you gave me this morning, it is identified as
23 expert opinion report May 26, 2010.

24 A. Right.

25 Q. Is that correct?

1 A. Yes.

2 Q. Is that your next --

3 A. My next what? Sorry, sir?

4 Q. Pardon? Is that your next report?

5 A. No. This is the prior report. This
6 looks to me like the prior report.

7 Q. Prior to?

8 A. Prior to this report (indicating).

9 Q. So are you telling me that Exhibit 141
10 was your first report?

11 A. Yes. Yes, there's no question.

12 Q. No question. How do you know that?

13 A. Take a look at -- I had a lot of place
14 keepers. I mean sections that I need to consider.

15 Q. I'm sorry, tell me how it is that you
16 concluded that Exhibit 141 was drafted before?

17 A. Well, in quickly looking at it, you
18 know, it looks like this is a more complete document
19 and more filled in than this one. This one
20 meaning -- okay. The one document that has all of
21 the (indicating) --

22 Q. Look at the exhibit number and let's
23 get -- let's be clear on the record.

24 A. So what's -- what's your question,
25 sir?

1 Q. Exhibit 141, which I've just handed
2 you, is a subsequent draft of your expert report,
3 correct?

4 MS. CARTER: Objection.

5 A. No. This is a -- this precedes -- 141
6 precedes 140.

7 BY MR. KAPLAN:

8 Q. Okay. So 140 was a more advanced form
9 of your report?

10 A. Yes, that's correct.

11 Q. Okay. And even though you had an
12 initial -- prepared an initial draft which is 141.

13 A. Right.

14 Q. Then you got to 140 when you had time
15 to further review documents, right?

16 A. Or further review and -- and collect
17 my thoughts.

18 Q. And think about it, collect your
19 thoughts, be comprehensive?

20 A. Yes.

21 Q. And -- and Exhibit 140, the draft
22 report that came after the initial draft report, you
23 said nothing about Mylan, right?

24 A. That is correct.

25 Q. Okay. Well, let's look at 141 which

1 you say was your initial draft report; is that
2 right?

3 A. Yes.

4 Q. Summary of the opinions is on page 1.
5 And there is nothing, there is no opinion
6 whatsoever, is there, as to Mylan?

7 A. That is correct.

8 Q. On Page 2, you state in the
9 introduction that it's not only you but it's Mark
10 Kenny and Salvatore Romano who have been engaged by
11 Motley Rice to prepare an expert report?

12 A. That is correct.

13 Q. That you, Mark Kenny, and Salvatore
14 Romano had been engaged to participate in a legal
15 deposition?

16 A. That is correct.

17 Q. And that you, Mark Kenny, and
18 Salvatore Romano, have been engaged to testify as an
19 expert witness at trial?

20 A. Yes.

21 Q. And then you refer to the expert
22 opinion as "our expert opinion," right?

23 A. That is correct.

24 Q. So in the -- in the subsequent draft
25 which is marked as Exhibit 141 -- I'm sorry.

1 In the initial draft, you make it clear
2 that this is going to be a joint report from you and
3 Sal, that you're both going to be experts to testify
4 at deposition and trial?

5 A. Correct.

6 Q. And then you pull that idea down in
7 the -- in the second draft which is 141?

8 A. Correct.

9 Q. Okay. To -- to be correct, and make
10 sure that -- if you look at Exhibit 140, which you
11 said was the subsequent draft?

12 A. Right.

13 Q. You say in there too on page 5 that
14 it's you and Sal Romano?

15 A. Right, and his name appears on the
16 front.

17 Q. Yeah. So let's look at what you say
18 is your initial report, Exhibit 141, which you
19 agreed says nothing about Mylan in the summary of
20 your opinion, right?

21 A. Correct.

22 Q. And that's in -- that's in a black box
23 on the first page, right?

24 A. Black box?

25 Q. First page of 141?

1 A. Oh, the box.

2 Q. Summary of opinion, black box, right?

3 Isn't that right?

4 A. Yes.

5 Q. And if you look at page 14 where it
6 says "SpyGlass Group Conclusion." Do you see that?
7 On Exhibit 141?

8 A. Yes.

9 Q. Nothing there pertaining to Mylan, is
10 there?

11 A. Nothing.

12 Q. Then look at page 16. There's a
13 heading, "Overall observations of the quality system
14 at Actavis." Underneath that, there is a note,
15 "Mark, we need to write a dialogue followed by
16 bullet points on the following."

17 Who do you think that is from? Would it
18 be Sal Romano?

19 A. Yes.

20 Q. So Sal Romano, who you described
21 earlier as somebody who just checked your spelling
22 and was a proofreader, was giving you substantive
23 input as to the content of your report?

24 A. He attempted to. He attempted to give
25 me substantive information of which I eliminated all

1 of it because I -- because I wanted input only into
2 spelling, format, completeness.

3 Q. So you threw out what his input as to
4 substantive content of your report?

5 A. Well, it was not substantive comment.
6 It was -- I had no interest in it.

7 Q. Okay.

8 A. Because I was the one that was going
9 to write the report and I was the one that was going
10 to testify, not him.

11 Q. Exactly. So on page 16 of the initial
12 draft report marked Exhibit 141, when Sal Romano
13 said to you, "We need to write a dialogue followed
14 by bullet points on the following," and if you look
15 down to the fifth and sixth bullet points or the
16 fifth bullet point, it says, "Mylan was negligent in
17 controlling its contractor, Actavis. Lack of
18 visits, audits, and follow-up. That was his
19 direction to you, right? Incorporate that in a
20 bullet point. He told you to do that, didn't he?

21 MS. CARTER: Objection.

22 A. I need to read it, sir.

23 BY MR. KAPLAN:

24 Q. Do you see the fifth bullet point?

25 A. Yes, sir.

1 Q. That is Sal telling you to put this
2 bullet point in saying Mylan was negligent in
3 controlling its contractor, Actavis, lack of visits,
4 audit, and follow-ups. That's what it says, isn't
5 it?

6 A. Yes.

7 Q. But when you prepared the subsequent
8 report marked Exhibit 140, you rejected that and
9 didn't include such a bullet point, did you?

10 A. At that point, I did not include it,
11 that's correct, because I threw out basically
12 anything that he told me.

13 Q. Well, if you look at Page 18 of your
14 final report dated June 15, 2010, you didn't reject
15 his first bullet point, did you? Do you have your
16 final report in front of you?

17 A. Yes.

18 Q. You accepted some things he told you
19 and you rejected others. Right?

20 MS. CARTER: Objection.

21 BY MR. KAPLAN:

22 Q. Are you looking on Page 18 of your
23 final report?

24 A. That is correct. That is correct
25 in -- could you ask the question --

1 Q. Did you say that the corporate culture
2 was production at any cost and ignore the quality
3 systems?

4 A. Did I say that? No, these were --
5 these were Sal's ideas.

6 Q. And did you incorporate that on Page
7 18 of your final report?

8 A. Some of the information I did
9 incorporate after review of the documents.

10 Q. Specifically, I'm looking at the first
11 bullet point and asking you whether you accepted
12 Sal's direction as to the substantive content of
13 your final report when he suggested that you say,
14 "the corporate culture was production at any cost
15 and ignore the quality systems." You said that as
16 to Actavis, didn't you?

17 MS. CARTER: Objection.

18 A. Yes.

19 BY MR. KAPLAN:

20 Q. So you accepted that?

21 A. I accepted it because I agreed with
22 it.

23 Q. Okay. And then look on the second and
24 third bullet points, page 14 of your final report,
25 includes his suggestions that you say that "Actavis"

1 corporate and QA management was weak and not
2 knowledgeable of the CGMP." You said that in your
3 final report, didn't you?

4 A. Not in my final report.

5 Q. Okay. Look on page 14, the last
6 paragraph, you make the statement, "It is my opinion
7 to a reasonable degree of certainty that corporate
8 and QA management were not knowledgeable of the
9 CGMP."

10 A. Yeah. I didn't say anything about
11 weak. Those are not terms that I would use.

12 Q. So we're going to parse out the word
13 "weak"?

14 A. No, it's an important word.

15 Q. Okay. But you did follow the
16 suggestion to include the statement that "Actavis'
17 corporate and QA management were not knowledgeable
18 of the CGMP." Except to that, right?

19 MS. CARTER: Objection.

20 A. I accepted that because it agreed
21 with --

22 BY MR. KAPLAN:

23 Q. Same with -- same with the next bullet
24 point. With regard to Sal's direction as to the
25 substantive content of your report telling you that

1 you should say that many drug products were made and
2 sold without approved NDAs/ANDA showing arrogance or
3 a complete lack of knowledge of regulatory
4 requirements?

5 A. I never did anything with that --

6 MS. CARTER: Objection.

7 A. Ultimately.

8 BY MR. KAPLAN:

9 Q. Look at your final report, page 14.
10 Your final report is Exhibit 38. Do you have that
11 in front of you? Page 14. Look at the last full
12 paragraph. You parrot Sal Romano's words that say
13 "Additionally, there was a lack of understanding of
14 the regulatory approval process since many drug
15 products were made and sold without approved
16 NDA/ANDAs." Right?

17 MS. CARTER: Objection.

18 A. I don't recall, to be honest with you.

19 BY MR. KAPLAN:

20 Q. Well, just look at -- look at the
21 words. You don't have to recall anything, you just
22 have to look at page 14.

23 A. Fourteen, which bullet?

24 Q. Page 14 of your final report, Exhibit
25 38?

1 A. Which bullet?

2 Q. There's no bullet. It's Exhibit 38.

3 A. Oh, here, yeah. So I understand, I
4 want to read what you're saying that I parroted.

5 Q. You parroted these words, "many drug
6 products were made and sold without approved
7 NDAs/ANDAs," I think you eliminated the words
8 "showing arrogance." But then you used "evidencing
9 a complete lack of knowledge or regulatory
10 requirements."

11 MS. CARTER: He's on the wrong page on
12 that one.

13 BY MR. KAPLAN:

14 Q. Are you on page 14 of Exhibit 38,
15 your final report dated June 15, 2010?

16 A. Yes, but I'm on the wrong page when it
17 comes to this, I guess (indicating).

18 Q. Look on page 16 of your initial draft
19 report.

20 MR. ANDERTON: Exhibit 141.

21 BY MR. KAPLAN:

22 Q. Yes. Where Sal Romano is giving you
23 direction on the content of the report?

24 MS. CARTER: Objection.

25 A. Okay. Could you please show me? I'm

1 looking at page 16.

2 MR. ANDERTON: You're on Exhibit 140,
3 go to 141, Page 16 of Exhibit 141.

4 A. Got it.

5 MR. ANDERTON: Look at the third
6 bullet point.

7 A. And your question is? One more time
8 so I understand it.

9 BY MR. KAPLAN:

10 Q. That's fine. Let's go through it.

11 A. Sure.

12 Q. If you're looking at page 16 of
13 Exhibit 141 where Sal Romano is giving you direction
14 as to the suggested content of the expert report to
15 be submitted in this case, in the third bullet
16 point, he says that you need to say the following:
17 "Many drug products were made and sold without
18 approved NDA/ANDA showing arrogance or a complete
19 lack of knowledge of regulatory requirements."

20 He's suggesting that you say that as to
21 Actavis, right?

22 MS. CARTER: Objection.

23 A. He's saying that that's his opinion.

24 BY MR. KAPLAN:

25 Q. Right. And then in your final report

1 which is Exhibit 38, on page 14, you say as follows:

2 "Apparently, there was a lack of understanding of
3 the regulatory approval process since many drug
4 products were made and sold without approved
5 NDA/ANDAs," citing footnote ten. Isn't that what
6 you said --

7 A. Yes.

8 Q. -- in your final report?

9 A. That is in my final report.

10 Q. So you followed the direction of Sal
11 Romano as to the substantive content of your final
12 report on that issue, didn't you?

13 MS. CARTER: Objection.

14 A. I agreed with Sal. I did not follow
15 his direction. There's a big difference.

16 BY MR. KAPLAN:

17 Q. You adopted Sal's characterization
18 that Actavis demonstrated or showed arrogance,
19 right?

20 MS. CARTER: Objection.

21 A. Sal?

22 BY MR. KAPLAN:

23 Q. Look at the fourth bullet point on
24 page 16 of Exhibit 141 where Sal Romano is saying to
25 you, "We need to write a dialogue followed by bullet

1 points on the following," and the third bullet
2 point, he uses the term "showing arrogance"?

3 A. Right.

4 Q. And you -- you adopted those words,
5 didn't you, in your final report on page 14?

6 A. I wrote similar content. I didn't
7 write -- I didn't write the same words, I'm sure.

8 Q. Quote, page 14 of your report June 15,
9 2010, Exhibit 38, "It is my opinion to a reasonable
10 degree of certainty that they" -- meaning Actavis --
11 were highly resistant to systematic change,
12 appearing sure that minor improvements would resolve
13 all of their issues. This was a flawed strategy.
14 Their arrogance resulted in managing a drug company
15 that operated at a high risk level." Correct?

16 A. Correct what?

17 Q. Isn't that what you said?

18 A. That's what I said.

19 Q. You followed Sal's direction as to the
20 content of your report?

21 MS. CARTER: Objection.

22 BY MR. KAPLAN:

23 Q. Didn't you?

24 A. We had -- we had discussions. Sal did
25 not direct me, nobody directs me. We had technical,

1 if you will, professional discussions. From that, I
2 made conclusions. It's that simple. I was being
3 respectful at that point.

4 Q. So you were being respectful by
5 including what Sal told you to say in your final
6 report?

7 A. I was being respectful and listening
8 to him.

9 MS. CARTER: Objection.

10 BY MR. KAPLAN:

11 Q. And adopting --

12 A. No. I was not being respectful and
13 adopting, I was being -- if I agreed with it, I
14 wouldn't put it in. If I didn't agree with it, I
15 would not put it in.

16 Q. Let's look again at Exhibit 141 on
17 Page 16. This is your initial draft report in this
18 case. You see the heading review of "Actavis GMP
19 compliance history-all products"?

20 A. Yes.

21 Q. Below that in parenthesis is a note
22 from Sal Romano to you?

23 A. Right.

24 Q. "Mark, dot dot dot, I have added your
25 stuff on GMP. Please add some dialogue, dot dot

1 dot. I do not see -- I did not do a good fit of all
2 of your tables into this dock, exclamation point.
3 Maybe the table details should be as an attachment?
4 I think the following section on DIGITEK is good,
5 dot dot dot. Can you get this section in the same
6 bullet format?" And then the following section is
7 "SpyGlass Group conclusion result of FDA
8 documentation." Do you see that?

9 A. Yes.

10 Q. Would you agree that this is further
11 evidence that Sal Romano gave you direction as to
12 the substantive content of your final expert report
13 and opinions in this case?

14 A. Absolutely not. I would say that he
15 assisted in trying to help me organize it. Going
16 through and reviewing it and trying to make it into
17 a highly organized report and understandable.

18 Q. Sounds like he was more than a spell
19 checker or proofreader, doesn't it?

20 A. Helped me organize.

21 Q. Now -- now he's spell checker,
22 proofreader, and organizer?

23 A. Yeah. I mean, I guess I would say
24 yes.

25 Q. So I don't have any other draft

1 reports. I have exhibit 141 which were just talking
2 about which you told me is the initial draft report.
3 I have Exhibit 140 which you told me is the next
4 draft report?

5 A. Right.

6 Q. And then I have your final report
7 dated June 15, 2010?

8 A. Right.

9 Q. Are there any others?

10 A. No.

11 Q. Mylan's role was that of an authorized
12 distributor of record and wholesale distributor,
13 correct?

14 A. Correct.

15 Q. Under 21CFR 203.3, an authorized
16 distributor of record means the distributor with
17 whom a manufacturer has established an ongoing
18 relationship to distribute such manufacturer's
19 products, correct?

20 A. Okay. If you say -- I'm not familiar
21 with that phraseology.

22 Q. Would you like me to show you that
23 regulation?

24 A. Surely.

25 (Whereupon, Exhibit 142, Regulation,

1 was marked for identification as of today's
2 date.)

3 BY MR. KAPLAN:

4 Q. I'm going to hand you what we've
5 marked as Exhibit 142, which is 21CFR section 203.3,
6 subparagraph B, defines authorized distributor of
7 record. And I want you to take a look at that and
8 then read that into the record as soon as she marks
9 it.

10 A. And that's what number?

11 Q. 203.3b, as in boy, where it says
12 "authorized distributor of record." Do you see
13 that?

14 A. 203.

15 Q. Point 3, subparagraph B. What does it
16 say?

17 A. "Authorized distributor, distributor
18 of record."

19 Q. Read it.

20 A. "Authorized distributor of record
21 means a distributor with whom a manufacturer has
22 established an ongoing relationship to distribute
23 such manufacturers' products."

24 Q. So Mylan was an authorized distributor
25 of record?

1 A. I don't know that term.

2 Q. Well, you see it, I've just showed it
3 to you.

4 A. I see it, but I don't know the context
5 of this, and I am not the right person to give an
6 interpretation of the meaning of that.

7 Q. Isn't it important to you, fundamental
8 to your opinions in this case, to know what Mylan's
9 legal status and responsibility was?

10 A. I don't know if it's important or not,
11 sir.

12 Q. Well, you can't make up something
13 about their -- their legal duties and
14 responsibilities, can you?

15 A. I'm sorry?

16 Q. It's not Kenny on the law, it's what
17 the law is?

18 A. Correct. And the law is good
19 manufacturing practices, of which I understand
20 fully.

21 Q. I move to strike that because that
22 really makes no sense.

23 MS. CARTER: Objection.

24 BY MR. KAPLAN:

25 Q. Look at 21CFC 203.3, Exhibit 142,

1 subparagraph D, defining wholesale distributor, and
2 tell me if you agree that Mylan is not only -- is
3 both an authorized distributor of record and a
4 wholesale distributor according to the code of
5 federal regulations?

6 A. You said 203.3D, the next page?

7 Q. Double D.

8 A. Double D.

9 Q. Do you see that? Do you want to read
10 that?

11 A. "Wholesale distributor means any
12 person engaged in the wholesale distribution of a
13 prescription drugs -- I beg your pardon --
14 prescription drugs, including but not limited to
15 manufacturers, repackagers, own label distributors,
16 private label distributors, jobbers, brokers,
17 warehouse, including manufacturers and distributors'
18 warehouses, chain drug warehouses, and wholesale
19 drug warehouses, independent wholesale drug traders,
20 and retail pharmacies that conduct wholesale
21 distribution."

22 Q. Does that help you with respect to
23 understanding Mylan's role in this case?

24 A. No, it doesn't. I would have to --

25 Q. Just yes or no.

1 A. No, it does not.

2 Q. Are you aware of any regulation that
3 places a responsibility for compliance with
4 manufacturing GMPs on a wholesale distributor?

5 A. I'm not aware.

6 Q. Are you aware of any regulation that
7 requires wholesale distributors to establish quality
8 agreements with manufacturers or suppliers?

9 A. Regulation? I understand the certain
10 sections of the GMP and what the expectations and
11 requirements of the FDA are.

12 Q. Are you aware -- I'm going to ask you
13 the question again. Are you aware of any regulation
14 that requires wholesale distributors to establish
15 quality agreements with manufacturers?

16 A. Yes.

17 Q. Show me the --

18 A. I would show you the paragraph 22 of
19 21011122 where it talks about quality systems, and I
20 would interpret that to --

21 Q. Just -- just tell me what you refer
22 to, what you rely on?

23 A. I have to pull the GMP again. We
24 talked about it earlier.

25 Q. Give me -- give me the GMP that you're

1 talking about. I want you to show me in there where
2 it -- where it says that a wholesale distributor
3 must establish a quality agreement with a
4 manufacturer.

5 A. Okay. I would interpret --

6 Q. Just show me the language that says a
7 wholesale distributor must establish a quality
8 agreement with a manufacturer. Just read the
9 language there.

10 A. It does not say -- use the word
11 quality agreement.

12 Q. Thank you. And that regulation that
13 you have before you which has been previously marked
14 I believe as exhibit --

15 MS. CARTER: I think it's Plaintiff's
16 49.

17 BY MR. KAPLAN:

18 Q. Plaintiff's 49, is that included among
19 the documents that you relied upon in rendering your
20 opinions in this case which are contained in your
21 report of June 15, 2010?

22 A. Yes, it is.

23 Q. And where does that appear on the list
24 of references?

25 A. It's the second one, number two.

1 Q. Okay. That cites the entire 21CFR
2 part 210 and 21CFR part 211.

3 A. Right. So I did not specify what
4 sections within that.

5 Q. And this is the precise regulation you
6 are relying upon, right?

7 A. That is correct.

8 Q. Which says nothing about a quality
9 agreement?

10 A. It does not use those words.

11 Q. Thank you. Are you aware of any
12 regulations that requires wholesale distributors to
13 audit manufacturing companies?

14 A. I'm aware of the requirements of GMP
15 which is to select, qualify, and monitor your
16 suppliers of which that would -- in Mylan's case
17 would include Actavis.

18 Q. Are you aware, I'm going to ask you
19 again, of any regulation that requires a wholesale
20 distributor to audit a manufacturing company?

21 A. Using those specific terms, no.

22 Q. Are you aware of any regulation or law
23 that gives wholesale distributors the right to
24 inspect manufacturers for CGMP compliance?

25 A. No.

1 Q. Are you aware of any regulation that
2 requires a wholesale distributor to require a
3 certificate of analysis or certificate of
4 conformance from a manufacturer for finished
5 packaged product?

6 A. As stated, no.

7 Q. Are you aware of any regulation that
8 requires a wholesale distributor to perform periodic
9 chemical analysis of finished product purchased from
10 a manufacturer?

11 A. You're going to have to repeat that.

12 Q. Are you aware of any regulation that
13 requires a wholesale distributor to perform periodic
14 chemical analyses of finished product purchased from
15 a manufacturer?

16 A. In the regulations, it does not state
17 that specifically.

18 Q. Your final report in this case dated
19 June 15, 2010, previously marked as Exhibit 38, is a
20 lengthy one, isn't it?

21 A. It is the number of pages it is.

22 Q. The last numbered page is 50. Is that
23 correct?

24 A. Yes, it is.

25 Q. Less than a page of those 50 pages is

1 devoted to any discussion about Mylan, isn't it?

2 A. I believe that is correct, yes.

3 Q. You assumed that Mylan was the holder
4 of the ANDA?

5 A. No, I never assumed that.

6 Q. So you know that Mylan was not the
7 ANDA holder for DIGITEK?

8 A. That's correct, I knew that.

9 Q. And you know that Mylan was not the
10 manufacturer of DIGITEK?

11 A. They did not produce the product,
12 that's correct.

13 Q. Let me state it again. You know that
14 Mylan was not the manufacturer of DIGITEK?

15 A. That Mylan was not the manufacturer,
16 correct.

17 Q. Explain the basis for your assumption
18 that Mylan is required by GMP to investigate all
19 complaints as stated in -- on page 33 of your final
20 report dated June 15, 2010 previously marked as
21 Exhibit 38?

22 A. If I recall correctly, which I think I
23 do, the supply agreements stated that Mylan would
24 handle complaints which was a good thing that it was
25 stated. The -- since they took ownership of

1 complaint handling, they needed to do it in
2 accordance to good manufacturing practice and in
3 cooperation with the manufacturer.

4 Q. So you've read the supply and
5 distribution agreement?

6 A. Yes.

7 Q. And -- and you agree with me that it
8 has provisions in there about complaint handling?

9 A. Yes, I believe it does.

10 Q. Whose responsibility do you think it
11 was to handle the complaints?

12 A. I'm sorry.

13 Q. Whose responsibility do you think it
14 was to handle the complaints?

15 A. Well, there's -- there's a lot of
16 functions associated with complaints. The -- the
17 receipt of the complaints, the records of the
18 complaints, would side in two spots. One would be
19 in Mylan and the other would be in Actavis. Actavis
20 would engage in investigation if requested by Mylan.
21 If they weren't aware of a complaint, they couldn't
22 investigate it.

23 Q. Can you tell me what part of the
24 agreement you're referring to?

25 A. I don't recall.

1 Q. Do you want to take a look at it?

2 A. Sure.

3 Q. Why don't you do that.

4 A. I don't have the agreement here.

5 Q. Did you look at the supply and
6 distribution agreement?

7 A. Very early on. Yes.

8 Q. When did you last look at it?

9 A. It was probably one of the first
10 documents I looked at.

11 Q. How early in the process?

12 A. Very early.

13 Q. You told me just a few minutes ago
14 that when you drafted your initial report, you
15 didn't look at any Mylan documents?

16 A. I realized that I did afterwards.

17 Q. Have you misspoken yourself again?

18 A. Yes. I did look at it, I did see it.

19 Q. So when you -- when you drafted your
20 initial report and said nothing about Mylan, you had
21 already looked at the supply and distribution
22 agreement between Mylan and Actavis?

23 A. I had scanned through it.

24 Q. And when you -- when you drafted your
25 subsequent report, draft number two, you had looked

1 at the supply and distribution agreement between
2 Mylan and Actavis?

3 A. I had scanned at it at the original
4 time. I didn't scan it again.

5 Q. And still offered no opinion as to
6 Mylan?

7 A. That's correct.

8 Q. What was your -- what was your great
9 revelation then that caused you to --

10 A. I explained it earlier. I was asked
11 do I -- have I looked at the Mylan documents, and I
12 said, no, I have not looked at them.

13 Q. But now you just told me you had
14 looked at them?

15 A. Well, I looked at one document. I
16 don't remember where the supply agreement was.

17 Q. Maybe you had better rethink this
18 again because this is -- this is sworn testimony
19 that you're giving under oath, and I don't want you
20 to misspeak yourself.

21 A. I understand.

22 Q. You told me at the time that you
23 drafted the first two reports which led to the final
24 report?

25 A. Right.

1 Q. You hadn't looked at Mylan documents.
2 Now you say you had looked at the supply and
3 distribution agreement. What's -- what's the
4 correct testimony here?

5 A. I saw that particular document and I
6 recall that I did review it.

7 Q. When did you see that document?

8 A. As I said, very early on in the
9 process. I looked at it, I blitzed through it,
10 because I was seeking a quality agreement, not the
11 general terms of operating between two companies.
12 Because the supply agreement has nothing to do with
13 the area that I'm expert in unless it includes the
14 quality agreement type requirements and -- and
15 specification of responsibilities.

16 Q. What criticisms do you have of the
17 supply and distribution agreement?

18 A. I have no criticism of it. I -- you
19 know, I scanned through it. I would have no opinion
20 on it, it's an operations document. It's focused as
21 an operations document.

22 Q. It's what?

23 A. It's an operations document.

24 Q. What does that mean?

25 A. Associated with terms, financial terms

1 in general and a supply agreement.

2 Q. It contains provisions such as the
3 fact that Actavis shall remain responsible for
4 maintaining and fulfilling all regulatory
5 requirements, doesn't it?

6 A. Uh-huh. That would be common
7 terminology used.

8 Q. It provides for procedures in
9 reporting adverse drug experience information,
10 doesn't it?

11 A. It says that, yeah.

12 Q. That's important, isn't it?

13 A. Important to whom?

14 Q. Well, important to you as expert in
15 this case offering opinions against Mylan. That's
16 important, isn't it?

17 A. Is it important -- it's referenced in
18 there, but it's not the -- it's not what I'm looking
19 for. I'm looking for substantive, specific
20 information as to who's responsible for what and
21 going down to on a day to day level. Who is doing
22 what.

23 Q. Well, how about this --

24 A. Similar to the document that they
25 wrote, in other words, their draft is a reasonably

1 comprehensive document.

2 Q. How about this: Do you recall that
3 the supply and distribution agreement between Mylan
4 and Actavis provides that Mylan shall refer or
5 submit to Actavis all drug experience reports and
6 other medical inquiries or quality complaints
7 associated with the products within 48 hours of
8 Mylan's receipt of such reports?

9 A. Okay.

10 Q. Do you recall that?

11 A. I don't recall it specifically, but I
12 remember there was a complaint.

13 Q. Is that an appropriate provision?

14 A. I believe so.

15 Q. It says all telephone calls shall be
16 referred to Actavis. Is that appropriate?

17 A. It a legal -- situation -- I would
18 have no expert opinion on that particular aspect of
19 it.

20 Q. You don't have any criticism of that,
21 do you?

22 A. I have no criticism of it.

23 Q. It says, "Actavis shall be responsible
24 for fulfilling any regulatory requirements with
25 respect to such events, including but not limited to

1 the filing of all form FD 2253s, contact and
2 follow-up with the patient or reporter of the event
3 and will make any necessary contact with the FDA
4 regarding the subject matter of the same."

5 A. I'm not familiar with those terms. I
6 have no opinion on it.

7 Q. That places responsibility clearly on
8 the shoulders of Actavis, doesn't it?

9 A. I would have to study that further.
10 I'm not going to -- I don't think I can give an
11 opinion based upon reading one sentence out of a
12 supply agreement.

13 Q. The fact is you really haven't read
14 this supply agreement, have you?

15 A. I told you I scanned through it and I
16 looked for certain conditions which I did not find
17 in there. And the conditions that you're talking
18 about are not what I was not looking for.

19 Q. The supply and distribution agreement
20 between Actavis and Mylan provides that "Actavis
21 shall be responsible for filing and maintaining all
22 documentation and other information as required by
23 each and every state and locality for the purpose of
24 listing the products on each state's formulary or
25 other similar authority, and for obtaining such

1 approvals as may be necessary to sell the products
2 in those states."

3 Is that an appropriate provision?

4 A. I don't know what is appropriate or
5 not appropriate. It's a regulatory legal issue, not
6 a GMP issue under the GMP category.

7 Q. The supply and distribution agreement
8 between Actavis and Mylan which is dated August 5,
9 1999, provides that Actavis grants to Mylan the
10 exclusive right to market, sell, and promote and
11 distribute products. Is that your understanding?

12 A. Yes, that is my understanding.

13 Q. Anything wrong with that?

14 A. I can't say whether it's wrong or
15 right. It just is.

16 Q. The supply and distribution agreement
17 dated August 5 1999 between Mylan and Actavis
18 provides that "Actavis shall perform quality
19 assurance testing with respect to the products sold
20 hereunder." That is DIGITEK.

21 A. Right.

22 Q. "Including stability testing so that
23 the products conform with the specifications."

24 Anything wrong with that?

25 A. No, not that I can see.

1 Q. That places responsibility squarely on
2 the shoulders of Actavis, didn't it?

3 A. For that subject.

4 Q. The agreement further provides that
5 "Actavis shall provide the results of such tests to
6 Mylan in the form of a certificate of analysis."

7 Is that appropriate?

8 A. If they agree to it, certainly.

9 Q. What is a certificate of analysis?

10 A. The certificate of analysis is the
11 summary of all of the finished product testing
12 results.

13 Q. That's a good thing that the
14 certificate of analysis was being provided?

15 A. Absolutely.

16 Q. The supply and distribution agreement
17 between Mylan and Actavis dated August 5, 1999
18 provides that "Actavis will manufacture, package,
19 label, store, and ship the products," being DIGITEK,
20 that is the subject of the agreement. So Actavis
21 will "manufacture, package, label, store, and ship
22 DIGITEK in accordance with the specifications set
23 forth in the ANDA, and as such ANDA may be amended
24 from time to time."

25 Is that an appropriate provision in the

1 agreement?

2 A. It seems appropriate.

3 Q. Do you have any criticism of that?

4 A. I have no criticism.

5 Q. That seems to place responsibility
6 squarely on the shoulders of Actavis, doesn't it?

7 A. In that particular situation, yes.

8 Q. The agreement further provides that
9 "Mylan shall be promptly and fully advised of any
10 new instructions or specifications required by the
11 FDA or the FFDCA."

12 Is that appropriate?

13 A. I believe so.

14 Q. Further provides that "Mylan's quality
15 control personnel upon reasonable prior notice shall
16 be permitted to observe the manufacture of DIGITEK."

17 Is that appropriate?

18 A. Yes.

19 Q. Further provides that "in the event
20 Actavis cannot manufacture products in accordance
21 with the instructions and specifications, Actavis
22 shall promptly so advise Mylan."

23 Is that appropriate?

24 A. Yes.

25 Q. And further, that "Actavis shall not

1 change any ANDA or specification without the prior
2 written consent of Mylan." Appropriate?

3 A. Appropriate.

4 Q. Good practice?

5 A. Appropriate. It is a must practice.

6 Q. The supply and distribution agreement
7 of August 5, 1999 between Actavis and Mylan further
8 provides that "Actavis will package and label
9 products under the Mylan name and Actavis shall
10 provide all finished labeling for the products in
11 accordance with any applicable FDA or other
12 regulatory labeling requirements." Appropriate
13 provision?

14 A. I have no expertise on the subject,
15 but it appears appropriate.

16 Q. Any criticism of that?

17 A. No criticism.

18 MS. CARTER: For the record, when
19 you're reading it, you're changing Amide to
20 Actavis and Bertek to Mylan.

21 MR. KAPLAN: I sure am. And we
22 established that before, and he agreed with
23 me that any references to Amide, we would
24 call Actavis and any references to Bertek we
25 would call Mylan.

1 A. And that is appreciated.

2 BY MR. KAPLAN:

3 Q. Okay. So this supply and distribution
4 agreement, which by the way, was previously marked
5 as Exhibit M1 at the deposition of Susie Wolf, which
6 is one of the depositions that you didn't read, is a
7 document that you scanned early on in your review
8 here, right?

9 A. That's correct.

10 Q. Before you ever wrote a draft report?

11 A. Before, I don't know whether I wrote
12 the draft report or started. When we're talking
13 about a draft report, we're talking about the
14 beginning of the graphs, the matrices.

15 Q. And you were aware of the supply and
16 distribution agreement and reviewed it before you
17 drafted your first report. That's what your
18 testimony was?

19 A. I don't recall.

20 Q. Now you don't recall?

21 A. No. Honestly, I'm not sure if I did
22 it before or after. I look at hundreds of
23 documents. I don't remember whether I read it
24 before or after. That's unfair to ask me that. I
25 mean, it's unfair to expect me to remember that.

1 Q. I move that that answer be stricken as
2 not responsive.

3 Do you cite the supply and distribution
4 agreement among the references that you relied upon?

5 A. No, I did not.

6 Q. Did the FDA ever criticize Mylan for
7 violating CGMP regulations relating to the
8 distribution of DIGITEK?

9 A. I'm not aware of any.

10 Q. Did the FDA ever criticize Mylan in
11 connection with its distribution of Digitek?

12 A. I'm not aware of any.

13 Q. Did the FDA ever criticize Mylan with
14 respect to the recall of DIGITEK?

15 A. I'm not aware of any.

16 Q. Did the FDA ever criticize Mylan
17 regarding the handling of DIGITEK related
18 complaints?

19 A. I'm not aware of any.

20 Q. Has the FDA ever criticized Mylan's
21 vendor management or supplier management policies?

22 A. Again, I have no way of knowing.

23 Q. Has the FDA ever criticized any other
24 distributor in connection with the events
25 surrounding the 2008 Actavis recalls?

1 A. I don't know how I would have that
2 information, so I don't -- I would say I haven't
3 seen anything.

4 THE VIDEOGRAPHER: We're off the
5 record. The time is 4:24. This is the end
6 of tape 4.

7 (Recess taken.)

8 THE VIDEOGRAPHER: We're back on the
9 record. The time is 4:38. This is the
10 beginning of tape 5.

11 BY MR. KAPLAN:

12 Q. All right. You would -- you would
13 agree that current good manufacturing practices
14 which is abbreviated CGMP, also referred to as GMP,
15 is a law that is established in the code of federal
16 regulations, right?

17 A. Yes.

18 Q. That's the law?

19 A. That's the law.

20 Q. And it sets standards for a product to
21 meet specific requirements for identity, strength,
22 quality, and purity, correct?

23 A. That's a portion of it, yes, that's
24 correct.

25 Q. And it's a law that outlines the

1 requirements for every drug manufacturer to follow?

2 A. That's correct.

3 Q. That law has been continually improved
4 over the years since it was first adopted?

5 A. Slightly revised, but yes, it has
6 been. Yes, it has been improved.

7 Q. Has been continually improved?

8 A. Yes, that's correct.

9 Q. It's your opinion that the current
10 good manufacturing practice regulations are well
11 designed documents?

12 A. That is correct.

13 Q. The current good manufacturing
14 practice regulations are a great help in ensuring
15 that patients and customers receive 100 percent safe
16 and effective drug products?

17 A. Yes, that's correct.

18 Q. And it's your experience that the FDA
19 understands the business and fairly and impartially
20 uses a heavy hand only when they fear public safety?

21 A. That's correct.

22 Q. And even in those high risk
23 situations -- well, in those high risk situations,
24 they continually escalate their concerns until all
25 public risks are resolved?

1 A. Yes, that is their objective.

2 Q. And -- and that's what they did in the
3 case of DIGITEK, in the DIGITEK recall, right?

4 A. I -- certainly they work with Actavis
5 and they escalated it to the point that you can't go
6 any further other than criminal prosecution, as far
7 as I could see.

8 Q. Well, they escalated their concerns
9 until all public risks were resolved?

10 A. Right. Well put. Correct.

11 Q. In fact, that's how you put it on page
12 8 of your report of June 15, 2010, isn't it?

13 A. Okay. If it says that. I don't have
14 it in front of me.

15 Q. It is what you said?

16 A. Okay. I trust you.

17 Q. And then the FDA, following the
18 resolution of risks to public safety with regard to
19 DIGITEK, published a document which is posted on the
20 FDA Website on the Internet titled, "facts and myths
21 about generic drugs."

22 A. Yes.

23 Q. And you are familiar with that
24 document, aren't you?

25 A. Reasonably familiar. I've read it.

1 Q. Well, let me read a portion to you.
2 "Myth, there are quality problems with generic drug
3 manufacturing. A recent recall of generic Digoxin,
4 called DIGITEK, shows that generic drugs put
5 patients at risk. Fact, FDA's aggressive action in
6 this case demonstrates the high standards to which
7 all prescription drugs, generic and brand name, are
8 held."

9 Would you agree with that?

10 A. Can I read it again? I would rather
11 read it than hear you say it. Can I read it,
12 please?

13 Q. I'm just asking whether you agree with
14 that statement?

15 A. I understand that. I would like to
16 read it.

17 Q. I'm going to ask the question and I
18 would like you to answer it. "FDA's aggressive
19 action in this case demonstrates the high standards
20 to which all prescription drugs, generic and brand
21 name, are held?"

22 A. I would say I agree with that.

23 Q. The FDA, you acknowledge, has an
24 abiding interest in public safety?

25 A. Most assuredly.

1 Q. Said "since the detection of the
2 manufacturing problem with DIGITEK, FDA has been
3 actively engaged with Actavis to ensure that all
4 potentially defective lots of DIGITEK have been
5 recalled."

6 Could you agree that they did that?

7 A. They appear to have done that.

8 Q. And then the FDA said, and continues
9 to say in the document entitled, "facts and myths
10 about generic drugs" posted on the FDA's Website,
11 the FDA says, "In our best judgment, given the very
12 small number of defective tablets, it may have
13 reached the market. The lack of reported adverse
14 events before the recall, harm to patients was very
15 unlikely."

16 A. I can't argue with that or -- I don't
17 know what would harm a person. So the term "harm"
18 takes it away from something I would have an opinion
19 for.

20 Q. In appendix F to your report of
21 June 15, 2010, pages 47 through 50, the heading is,
22 "FDA observations and events." You would agree with
23 me that there is no mention of Mylan in there,
24 correct?

25 A. That is correct.

1 Q. And you would agree with me that in
2 your final report dated June 15, 2010 on page 35
3 under the heading of "expert witness final summary,"
4 there is no mention of Mylan?

5 A. There is no mention of Mylan.

6 Q. You would also agree with me that on
7 pages 5 and 6 of your final report dated June 15,
8 2010 under the heading, "introduction," there is no
9 mention of Mylan?

10 A. That is correct.

11 Q. And you would also agree with me that
12 on page 7 of your final report dated June 15, 2010
13 under the heading, "work plan," there is no mention
14 of Mylan?

15 A. That is correct.

16 MR. KAPLAN: Off the record.

17 THE VIDEOGRAPHER: We're off the
18 record the time is 4:48.

19 (Recess taken.)

20 THE VIDEOGRAPHER: We're back on the
21 record. The time is 5:03.

22 EXAMINATION BY MR. ANDERTON:

23 Q. Mr. Kenny, my name is Michael
24 Anderton. I'm here on behalf of the Actavis
25 defendants. We've met, correct?

1 A. That's correct.

2 Q. All right. I'm going to ask you some
3 questions. We're going to cover some topics that
4 you've already cover with Mr. Kaplan, and perhaps
5 even some that we've covered a little bit in your
6 prior deposition session. I know Mr. Kaplan didn't
7 go over this, but just to kind of remind you, if I
8 ask you a question and you don't understand it,
9 please make sure that you let me know that.

10 A. Yes.

11 Q. So that you and I have an
12 understanding of what I'm asking and what you are
13 answering before you give an answer. Is that all
14 right?

15 A. Yes.

16 Q. Okay. So if you answer a question, I
17 will assume that you understood it. Is that fair?

18 A. Yes.

19 (Whereupon, Exhibit 143, E-mails, was
20 marked for identification as of today's
21 date.)

22 Q. All right. I am looking at a document
23 that has been marked as Exhibit 143, and it is a
24 stack of e-mails that you received -- I'm sorry --
25 that you provided to us from your -- from the

1 documents that you brought with you today?

2 A. Yes.

3 Q. That weren't in this yellow folder?

4 A. Okay.

5 Q. And the yellow folder was marked

6 Exhibit 110?

7 A. Right. It was in another folder.

8 Q. Right. That's fine. I'm going to ask
9 you some questions about both groups, some e-mails
10 in both groups. This is a different stack. Do you
11 remember giving us this stack?

12 A. Yes.

13 Q. All right. And I'm looking now at --
14 and eventually, we're going to leave this with the
15 court reporter and she'll make copies and we'll
16 all -- you'll get your back, or a copy back, at
17 least, and we'll all have a copy. But for now, we
18 don't have extra copies, all right?

19 A. Okay.

20 Q. I'm looking at an e-mail thread
21 that -- well, give me one second. Looking at an
22 e-mail thread -- or actually, a single page e-mail,
23 it starts on -- well, it's an e-mail thread. It
24 starts on February 19, an e-mail from Sandy Summers,
25 who is at Meghan Johnson's law firm, I believe she's

1 a paralegal or a legal assistant of some type,
2 forwarding to you and Mr. Romano a confidentiality
3 order and a letter of engagement?

4 A. Right.

5 Q. Does that mean that your engagement
6 with or on behalf of the plaintiffs started sometime
7 right around February 19 of 2010?

8 A. I believe that's correct.

9 Q. Does that sound about right?

10 A. Yes.

11 Q. And then on the 23rd of February,
12 there's further e-mail communication from
13 Ms. Johnson to you about the protective order and
14 about sending you documents. Another e-mail in this
15 stack -- actually, again, an e-mail thread, is dated
16 February -- the first e-mail in the thread is dated
17 February 24, 2010, so about five days after you
18 received the engagement letter to undertake work for
19 the plaintiffs?

20 A. Okay.

21 Q. And according to this e-mail, it's
22 from Sal Romano to Meghan Johnson and a copy to
23 SpyGlass. I assume that you have access to that
24 e-mail box?

25 A. Yes.

1 Q. Or the mail sent to that address?

2 A. Yes, I have access to it.

3 Q. And it says, "Mark and I have received
4 the dots on the CD. Thanks. We will be traveling
5 starting Friday until March 9. We intend to take
6 the dots with us and review them on the trip."

7 That means -- is that the first group of
8 documents you would have received from the
9 Plaintiff's counsel?

10 A. Yes, that's correct. The disk which
11 you -- you have.

12 Q. Okay. So the first group of documents
13 that you received was February 24, 2010?

14 A. Correct.

15 Q. And on that same day about an hour
16 after you received an e-mail from Ms. Johnson, you
17 responded to Ms. Johnson. Actually, you said to Sal
18 in an e-mail, "the actual batch records are
19 extremely important. Do you want me to request the
20 information?" Do you remember making -- sending
21 that e-mail?

22 A. I don't remember, but I'm sure I put
23 that down. No, I don't remember the e-mail.

24 Q. All right. And within a matter of
25 moments, Mr. Romano e-mailed Mrs. Johnson at 3:48 on

1 February 24, the same day you got the first disk,
2 and said, "Mark and I believe the batch records will
3 be critical for us to review. How many batches were
4 recalled? Do you have all the batch records as PDF
5 files? We have lots to read now, but I think we'll
6 have to take a look at the batch records soon.
7 Thanks Sal." And your -- again, that SpyGlass
8 e-mail address is copied on that document?

9 A. I understand.

10 Q. Do you remember Mr. Romano sending
11 that e-mail?

12 A. No, I don't but it makes sense. I
13 mean I --

14 Q. All right. So the first day that you
15 got document from the plaintiff's counsel, you
16 immediately responded and said we need to see the
17 batch records?

18 A. Correct.

19 Q. And in response, Ms. Johnson says we
20 have the batch records. She says later that day,
21 and I'll just read it so that it's accurate. "I
22 just got Mark's message and tried to call him back.
23 We do have the batch records but there are
24 approximately 170 plus batches for Digoxin. So
25 that's quite a bit of paperwork for a review on your

1 trip. I'm here for at least the next hour or so.

2 Give me a call if you have a chance. Thanks."

3 A. Right.

4 Q. So she responded to your e-mail by
5 essentially saying that's an awful lot, are you sure
6 you want to read that; is that right?

7 A. Yes, that's correct.

8 Q. And she never did send you those batch
9 records, did she?

10 A. I don't think I ever saw them.

11 Q. All right. So you asked for the batch
12 records and identified them as absolutely critical,
13 and the Plaintiff's counsel responded by saying we
14 don't think you should review them?

15 A. No, that's not what they said. What
16 they said is we got a lot, if you want to see them,
17 you know, we'll give them to you. And at that
18 particular point, early on and in -- I don't know if
19 you call it the discovery process, but of documents
20 I would like to see, that was clearly one of those
21 documents that I thought at that point I wanted to
22 see.

23 Q. And how -- and in fact -- well, how
24 did it come to be that the batch records weren't
25 critical?

1 A. When I do an audit, I'm looking for
2 exceptions. I found so many exceptions in the three
3 batches that I looked at I could make conclusions
4 off of that. I couldn't make conclusions that every
5 batch record was wrong, but I could make conclusions
6 that the batch records that I reviewed demonstrated
7 significant GMP issues.

8 Q. For those batches?

9 A. For those batches.

10 Q. So you couldn't make any conclusions
11 about any of the other batches?

12 A. It would be difficult in general.

13 Q. Let's talk about -- I guess I just
14 want to make sure I have a clear understanding of
15 the timing, and actually, just give me one second.
16 I want to make sure that I have a clear
17 understanding of the timing of Mr. Romano's
18 involvement. Your testimony has been repeatedly
19 that the original intention was that you and
20 Mr. Romano were going to be jointly engaged both to
21 draft the report and to testify, correct?

22 A. That is correct.

23 Q. And so that's how the engagement
24 certainly started, right?

25 A. Yes.

1 Q. And we see from the billing records
2 that Mr. Romano was billing substantive time on this
3 engagement beginning at the beginning of the
4 engagement in the February, March, April time frame,
5 and that continued all the way through June,
6 correct?

7 A. Correct. We started the same time
8 approximately.

9 Q. And in a -- now, this is where I'll
10 need you to take out the three versions of your
11 report that we've been talking about as exhibits and
12 kind of have them side by side. All right? You
13 have the final version that is I believe Exhibit 38,
14 as Mr. Kaplan identified that correctly?

15 MR. KAPLAN: I think it's actually 48.

16 THE WITNESS: I have my own copy, but
17 it's the same thing.

18 MR. KAPLAN: I do believe that the
19 exhibit -- that the final report dated
20 June 15, 2010 was previously marked as
21 Exhibit 48, and I probably misspoke myself.

22 MR. ANDERTON: More than once
23 probably.

24 MR. KAPLAN: Probably more than once.
25 So if the record can be corrected, I think

1 it was Exhibit 48, and we can check that.
2 And the other thing where I think I misspoke
3 perhaps was on the exhibit "facts and myths
4 about generic drugs." I know that has been
5 previously marked, and I think that was
6 previously marked as Exhibit 38.

7 A. I have 141.

8 BY MR. ANDERTON:

9 Q. So although there was some confusion,
10 Mr. Kenny, about some of your earlier testimony, as
11 I understand your current testimony, it is that what
12 has been marked as Exhibit 141 was your first draft,
13 right?

14 A. I believe that is correct, yes.

15 Q. And we know from the fact that we got
16 this off of a CD that you gave us this morning that
17 this was identified by you as a May 26, 2010 draft?

18 A. Correct.

19 Q. So as of -- and in the -- on Page 2 of
20 this draft, it still clearly indicates that
21 Mr. Romano and you have been engaged to draft the
22 report and provide expert testimony, right?

23 A. That's correct.

24 Q. So as of May 26, we know he is still
25 actively engaged, and the intention is that he will

1 draft and testify?

2 A. Yes.

3 Q. And if you look at Exhibit 140 which
4 you believe is a draft prepared after --

5 A. Right.

6 Q. -- Exhibit 141. And again, if you
7 look at -- one second. Page 5 of Exhibit 140, will
8 you look at that page, please?

9 A. 140, yes.

10 Q. You see that it also says -- still --
11 still indicates that Mr. Romano will be
12 participating in drafting the report and testifying,
13 correct?

14 A. Correct.

15 Q. So this is sometime after May 26,
16 right?

17 A. Sometime after, I can't tell you when.

18 Q. Well, we know that you met plaintiff's
19 counsel in early June in person, right?

20 A. Early June? We met in New York City
21 in person.

22 Q. Sometime in early June?

23 A. I don't remember -- if I looked at --
24 you know, my billing it will show. Also.

25 Q. Why don't you do that. You've got

1 that, right? Let's figure out when you met with the
2 Plaintiff's counsel. You said there were two
3 meetings face-to-face, right?

4 A. Yes.

5 Q. Were those meetings after you had
6 already prepared a draft?

7 A. The first one was not. The second
8 one, I had started the document at that point.

9 Q. Okay.

10 A. I don't recall how far along that
11 document was.

12 Q. Why don't you look at your time and
13 see if you can figure out when you met with the
14 plaintiffs in person.

15 A. There was a meeting on May 5th.
16 May 5th, but I can't tell you if that was a phone
17 meeting or a physical meeting. I can't tell you
18 from this, so far. I can continue to try.

19 Q. Well, let's -- actually, let's try
20 this another way. I'm looking again at the
21 documents in Exhibit 143, one of which is an e-mail
22 dated May 28, 2010 from Ms. Johnson to both you and
23 to that SpyGlass e-mail address, talking about a
24 Friday morning, June 4 meeting at the Newark
25 airport?

1 A. Newark airport, yes.

2 Q. Does that make it seem likely that you
3 met with Plaintiff's counsel in-person at the Newark
4 airport?

5 A. I did.

6 Q. On June 4th?

7 A. June 4th, if it says that, yes.

8 Q. Okay. And Mr. Romano attended that
9 meeting, right?

10 A. That's correct.

11 Q. And as we understand from Mr. Romano's
12 earlier -- from something we saw earlier, an e-mail
13 from Mr. Romano to plaintiff's counsel, part of the
14 discussion at that June 4th meeting was to talk
15 about strategy, right?

16 A. That's correct.

17 Q. And --

18 A. What Sal referred to as strategy.

19 Q. Okay.

20 A. In using his terms. To me it was a
21 status check, where are we, you know, what's the
22 next step.

23 Q. Well, this -- this document that is
24 marked as Exhibit 140 that is a draft that contains
25 handwritten notes, your handwritten notes, that you

1 now have acknowledged or that you previously
2 acknowledged and today forgot and now have
3 reaffirmed, reflect at least some comments of the
4 Plaintiff's counsel. Did you have that draft with
5 you at that June 4th meeting?

6 A. I had a draft with me at the June 4th
7 meeting, yes, I did.

8 Q. And did you discuss that draft with
9 the Plaintiff's counsel at that June 4th meeting?

10 A. In principle, we discussed it.

11 Q. What do you mean by "in principle"?

12 A. Principle. Well, what are your
13 findings? Did you look at XYZ, did you look at all
14 the attachments associated with -- because I was
15 having a lot of problems, as was Sal, with the
16 Crivella database. It's very hard to navigate. So
17 you find out later that there are documents in it
18 that you didn't realize were in it. And so -- so
19 there were questions as to did we review certain
20 information. That was the -- yes. That was the
21 conversation.

22 Q. And plaintiffs had seen a draft at
23 that time, right?

24 A. They did not see a draft at that time.

25 Q. When did they first see a draft?

1 A. We had a draft there. The draft was
2 scanned over about a 30 second period by Mike.
3 Meghan did not see the draft. That was -- that was
4 the extent of his review of that document. So he
5 did see it, but he saw it in terms of format. I
6 don't know if he could have read it in 30 seconds.

7 Q. You mentioned a moment ago that you
8 and Mr. Romano were having difficulties with the
9 Crivella database. That's some sort of hosting
10 environment where the plaintiffs hosted various
11 documents and they made them available to you and
12 Mr. Romano?

13 A. That's correct.

14 Q. So as of June 4 when you met with
15 plaintiff's counsel, you and Mr. Romano, you were
16 both still accessing and reviewing documents on the
17 database?

18 A. We were accessing documents, yes.

19 Q. And reviewing them?

20 A. Reviewing, sure.

21 Q. Including Mr. Romano?

22 A. He was still doing it. To a lesser
23 extent -- I don't remember if he was doing it or
24 not, to be honest with you. I was. I was.

25 Q. You said -- I mean, the record will

1 show what you said a moment ago, Mr. Kenny, but your
2 testimony not three moments ago was that both you
3 and Mr. Romano were having difficulty accessing
4 documents.

5 A. That's correct.

6 Q. You wouldn't have difficulty accessing
7 if you weren't trying, right?

8 A. Right. That's a good point.

9 Q. So the handwritten notes on Exhibit
10 140, I believe you also said early, as you responded
11 to questions by Mr. Kaplan, that those notes
12 reflected, at least in part, comments or thoughts
13 inquiring about whether you had reviewed certain
14 documents, right?

15 A. Could you repeat that? Please repeat
16 the question.

17 Q. Could you read that back, please?
18 (Record read.)

19 A. That was a portion of that discussion.

20 Q. Well, I want to be clear, now. The
21 notes that --

22 A. Oh, do you mean the notes that are on
23 here, did they reflect the conversation that I had
24 that talked about the documents, the additional
25 documents that I should review or look at? It does

1 not include that.

2 Q. I want to just make sure this part is
3 clear, okay?

4 A. All right.

5 Q. You answered some questions by
6 Mr. Kaplan about these notes earlier. And the
7 record will show what your answers were. To the
8 best of my recollection, one of the things you --
9 one of the characterizations that you gave to these
10 handwritten notes on Exhibit 140 is that they
11 reflected, at least in part, your notes about
12 comments that Plaintiff's counsel had made where
13 they were asking you if you had reviewed certain
14 documents or certain categories of documents. Do
15 you remember giving that testimony?

16 A. Yes, I do.

17 Q. Okay. And that is the same type of
18 discussion that you had at that June 4th meeting
19 with Plaintiff's counsel, right?

20 A. Yes, but it's hard to remember.

21 Q. Well, you now said yes twice that that
22 is one of the things that you discussed at that
23 meeting?

24 A. The content, yes. What was in the
25 content, most definitely.

1 Q. Okay. And does that make you more
2 able to tell whether the handwritten notes that you
3 put on this copy were made at the June 4th meeting
4 that you had with Plaintiff's counsel?

5 A. I don't think these were made at that.
6 I believe these were made between Sal and I. In my
7 house.

8 Q. Well, but you've already testified,
9 Mr. Kenny, multiple times, that these notes reflect
10 at least in part, comments made by Plaintiff's
11 counsel. You said that in your last deposition and
12 then you reaffirmed it after Mr. Kaplan pointed out
13 to you that you had overlooked that prior testimony.
14 So?

15 A. The reality is it's hard for me to
16 remember. I'm trying to put this thing together as
17 to what document I had, what did I write on down. I
18 don't remember. That's why -- and when I'm, let's
19 say refreshed, if you will, by prior testimony, it's
20 not coming together, I can't -- I can't tell you
21 with certainty regarding those conversations.

22 Q. Well, but as of June 4, Mr. Romano was
23 still attending meetings with Plaintiff's counsel?

24 A. That's correct.

25 Q. And it was still his intention to

1 participate in drafting the report and to testify?

2 A. I think it was his intention.

3 Q. And so actually, your testimony was
4 that the reason it was ultimately decided that he --
5 Mr. Romano would not participate to that degree is
6 because he had a conflict with his schedule and
7 would have been the commitments of the litigation if
8 he had participated to that extent, correct?

9 A. That's what he said.

10 Q. Well, is that -- is that your
11 understanding of what happened?

12 A. That's what he told me. I have no
13 reason to question him.

14 Q. So then but for those scheduling
15 conflicts, he would have stayed on the report and
16 testified, right?

17 A. I don't know that he would have.

18 Q. Well, are you aware of any other
19 reason why he didn't, other than the scheduling
20 conflicts?

21 A. I think he -- yes, I think he had cold
22 feet.

23 Q. Cold feet?

24 A. Yes. I think that he did not want to
25 ultimately appear in a court case. That's what I

1 sensed.

2 Q. That's what you sensed. Did he say
3 that to you?

4 A. No.

5 Q. When -- when was the decision made?

6 A. I don't know. I really don't know.

7 Q. But it was made after June 4 and
8 before June 15 when you finalized the report, right?

9 A. Not necessarily, no. It could have
10 happened before that.

11 Q. How much before that?

12 A. Oh, it would have been a week or so
13 before.

14 Q. A week or so before what?

15 A. The June 4th. So it would have been
16 the end of May, beginning of June, somewhere around
17 there, where he determined that it didn't look like
18 he look -- he looked at his calendar, he's going to
19 Florida, XYZ. And he said I can't do this.

20 Q. Did you discuss that at the meeting
21 with Plaintiff's counsel at June 4?

22 A. We discussed that. I don't know if it
23 was discussed at June 4th. I don't know.

24 Q. Was it resolved by that meeting?

25 A. I don't remember. It might have been.

1 Q. Okay. But we know that we have a
2 May 26 draft and we have a draft that we know is
3 after May 26?

4 A. Right.

5 Q. And what we know is that in both of
6 those drafts, so at least one draft after May 26,
7 Mr. Romano is still indicated as part drafter and
8 somebody who will testify?

9 A. Well, I didn't take his name out, but
10 it was -- he was still as of May 25th, 26th, still
11 the intention was that this was would be a draft, a
12 report signed by both of us.

13 Q. Okay. And when -- now, let's look at
14 exhibit -- give me one second. Let's look at
15 Exhibit 141, which again, you've identified as the
16 first draft of your report. And turn to page 16,
17 please.

18 A. Sixteen.

19 Q. Yes. I want to ask you some more
20 questions about the bullet points that Mr. Kaplan
21 asked you about earlier. And first, with respect to
22 the parenthetical, the first one under the "overall
23 observations" heading. Do you see that
24 parenthetical?

25 A. Yes.

1 Q. It says, "Mark, we need to write a
2 dialogue followed by bullet points on the
3 following." You said those are Mr. Romano's
4 comments, right?

5 A. Those are his comments.

6 Q. And he's telling you what to add to
7 the report, right?

8 A. He's making a suggestion.

9 Q. Well, it's not a suggestion; he's
10 telling you what to add to the report?

11 MS. CARTER: Objection.

12 BY MR. ANDERTON:

13 Q. Isn't it?

14 A. He's telling me whether or not I
15 accept them is another story. He's telling me to
16 add these to the report. He feels it's substantive.

17 Q. And you said, you know, you keep
18 wanting to say that this is solely your report?

19 A. Yes.

20 Q. But as of June -- as of sometime after
21 May 26th, which is three months plus into the
22 process and within two and a half or three weeks
23 before the report is due, he is still being
24 indicated as a drafter and as somebody who is going
25 to testify?

1 A. Yes, he is.

2 Q. And so when you say you were the one
3 who was going to testify, that's not true as of the
4 time of this draft, is it?

5 A. It is true somewhere in June.

6 MS. CARTER: Objection.

7 A. I don't know when that decision was
8 made, I honestly don't.

9 BY MR. ANDERTON:

10 Q. Well, but --

11 A. It was a point where it became clear
12 that he was not going to testify. He did -- how he
13 communicated that, I don't recall, and when did he
14 communicate it.

15 Q. Well, speaking of communicating, we
16 now know that Plaintiff's counsel, Ms. Johnson,
17 Mr. Miller, et cetera, received a draft of your
18 report, correct?

19 A. They received it in a very late stage
20 report in June.

21 Q. How? How did they get it?

22 A. I sent it via -- did I fax it or
23 e-mail it? It was either faxed or e-mailed. I
24 don't recall.

25 Q. I have looked through the documents

1 that you produced that you have represented as the
2 communications between you and Plaintiff's counsel.
3 There is no transmittal cover e-mail or other
4 document indicating that you are transmitting a
5 draft or a copy of your draft report to Plaintiff's
6 counsel.

7 A. I understand.

8 Q. Did you overlook that?

9 A. No. It was done at the Jersey Shore.
10 We were on vacation and I -- Denise handled it, and
11 I believe it was faxed. I'm going to guess it was
12 faxed, but there was no intent to hide any
13 documents.

14 Q. Who did you go to the Jersey Shore
15 with?

16 A. My wife.

17 Q. How long were you there?

18 A. We were there probably a week or so.

19 Q. When?

20 A. Somewhere around Memorial Day.

21 Q. After or before?

22 A. After or before what?

23 Q. Memorial Day?

24 A. I have to pull my calendar. We have a
25 house down there, we go down there regularly.

1 Q. I'm just trying to establish when you
2 were at the Jersey Shore. When did you take your
3 vacation to the Jersey Shore in 2010?

4 A. I don't recall. We took -- it's not a
5 vacation. We go down there for a couple of days.
6 When you're consulting, you go whenever you want,
7 you're off, you go down. I went down there 15
8 times. There is nothing remarkable.

9 Q. Okay. But it was sometime around
10 Memorial Day?

11 A. Correct.

12 Q. Which is before June 4?

13 A. Yes.

14 Q. So Plaintiffs had that draft before
15 you met with them in person on June 4?

16 A. They had them -- wait a minute, wait a
17 minute. I think I'm screwing this thing up.

18 MS. CARTER: Just take your time.

19 A. On June 4th -- on June 4th, I had a
20 copy, I can't tell you exactly which copy. Of which
21 is the one that Mike -- scanned.

22 BY MR. ANDERTON:

23 Q. Mike who?

24 A. I'm losing it here. Pete Miller. I'm
25 sorry. Pete Miller scanned. I don't know what copy

1 that was, and he looked at it and then asked me a
2 couple of questions. He did not focus on it, he
3 didn't read it. He went like two seconds, two
4 seconds, two seconds (indicating). That's it.

5 Q. Are you saying he had his own copy or
6 he looked at your copy?

7 A. No. He would never saw a copy. I had
8 a copy.

9 Q. Mr. Kenny, you just told me that you
10 faxed or e-mailed a copy to the Plaintiff's counsel?

11 A. I e-mailed a copy.

12 Q. From the Jersey Shore sometime around
13 Memorial Day. June 4 is after Memorial Day.

14 MS. CARTER: Objection.

15 A. Yeah.

16 BY MR. ANDERTON:

17 Q. And now you are saying he never had a
18 copy. I'm confused.

19 A. Mike, I don't remember. The realty is
20 I don't remember the exchange, other than if I had
21 to sit there and say what was I sure of, I was sure
22 that I brought a copy to Newark airport. He took a
23 look at it, 30 seconds, on or about four days before
24 the finalization of that report. I sent a copy, I
25 guess it was via e-mail to Meghan. Pete got a copy

1 of it. Meghan got back to me and said -- had some
2 specifics, you know, some grammar kind of stuff, and
3 I believe Pete got back to me and questioned, either
4 questioned it before or at that point, about had I
5 looked at Mylan documents. I don't recall if it was
6 that or earlier.

7 Q. When Meghan got back to you, was
8 that -- how did she do that?

9 A. Meghan got back to me, we talked over
10 the phone.

11 Q. But you e-mailed them a copy of the
12 draft?

13 A. Yes, I did.

14 Q. All right. Again, I don't see that
15 e-mail in any of the e-mails that you provided?

16 A. I did my best to make copies of
17 everything.

18 Q. If I ask you to look again for the --
19 specifically for any e-mail whereby you transmitted
20 drafts to the Plaintiff's counsel, will you do that?

21 A. Sure.

22 Q. All right. So you'll do that sometime
23 in the next several days and follow-up with
24 Plaintiff's counsel and let them know whether you
25 come up with anything?

1 A. Sure.

2 Q. If you need to make a note, please do.

3 A. I am going to make a note.

4 Q. All right. Take your time.

5 A. Okay. Got it.

6 Q. So again, and again, the record will
7 reflect -- you know, your testimony will be
8 reflected in the transcript. When you were
9 discussing with Mr. Kaplan Exhibit 140 and your
10 characterization of whether these bullet points on
11 page 16 were substantive input from Mr. Romano or
12 whether you considered them and accepted them only
13 if you felt they were appropriate, you said you were
14 the one who was going to testify. But as of this
15 draft, that's not true, is it?

16 A. It probably is not true. It appears
17 not to be true.

18 Q. Okay. And in fact, as of the next
19 draft, Exhibit 141, whenever that was, sometime
20 after May 26, it's still not true, right?

21 A. I don't recall.

22 Q. Well, the document says --

23 A. I understand that.

24 Q. -- that he's going to testify and
25 identifies him as a drafter, right?

1 A. It most certainly does.

2 Q. Okay. And go down further on page 16.
3 The second parenthetical from Mr. Romano, and I'm
4 going to read the beginning of it, it says, "Mark, I
5 have added your stuff on GMP. Please add some
6 dialogue." So he actually was adding things to the
7 report apparently?

8 A. He was next to me when we met, and he
9 would -- I would give him a copy, he would -- he
10 once, I believe only once, took the copy. He said
11 you do your thing, work with Crivella, read
12 documents. I'll do my thing. Take a look at this
13 thing, try to organize it. I had some of my own
14 thoughts, and ultimately, it came to this of which I
15 took this and then without his assistance, edited it
16 to what my opinion was.

17 Q. He says here he added stuff to the
18 report, his language?

19 A. No. He added my stuff. In other
20 words, it wasn't taken out -- I don't know what he
21 meant by it, to be honest with you.

22 Q. Wait a minute. You're drafting a
23 document?

24 A. Yes.

25 Q. And he says I have added your stuff on

1 GMP and you don't even know what that means?

2 A. Actually, I believe -- yeah, it means
3 the attachments I believe. I'm trying to recreate
4 this. Yes, it's the attachments, and that there was
5 no dialogue associated with the attachments. That
6 was his opinion. I don't recall if I ever did
7 anything about it.

8 Q. He then goes on to say, "I think the
9 following section on DIGITEK is good. Can you get
10 this section in the same bullet format?" Again,
11 adding substantive input to the report, right?

12 A. That's -- that is purely format, sir,
13 purely format. He liked the bullet approach.
14 That's all.

15 Q. Go back to page 13 of Exhibit 141,
16 please.

17 A. Page 13?

18 Q. Please.

19 A. Yes.

20 Q. And again, we know that this is
21 according to your testimony, your first draft,
22 right?

23 A. This is, yeah, my first draft.

24 Q. You see --

25 A. But it's -- I'm sorry. Go ahead, sir.

1 Q. You see the heading and then the first
2 full bullet point under the heading. The heading
3 reads, "Ineffective and unreliable methods," and
4 continues on from there. Do you see that heading?

5 A. Yes.

6 Q. And do you see the first bullet point
7 paragraph under that?

8 A. Yes.

9 Q. In that paragraph, you do an analysis
10 and make a comment on the reliability of visual
11 inspection.

12 Do you see that?

13 A. I do see that.

14 Q. And you actually gave testimony about
15 that in your earlier -- excuse me -- on June 29th at
16 your prior deposition session. Do you remember
17 that?

18 A. Yes.

19 Q. In this draft, you say that in your
20 opinion, visual inspection is only 80 percent
21 effective. Do you see that?

22 A. Yes.

23 Q. That is actually consistent with what
24 you testified to on June 29. Do you remember that?

25 A. Yes.

1 Q. In this draft, however, you actually
2 do a calculation and say that on the basis of your
3 position, you believe there are five double thick
4 tablets that weren't found, and that in your
5 opinion, apparently went undetected when the batch
6 was released. Do you see that?

7 A. Yes.

8 Q. So you actually at one point
9 formulated an opinion about exactly how many double
10 thick tablets you thought were still out there but
11 undetected?

12 A. I -- no. This is not -- this is --
13 Sal put that in there, not me.

14 Q. Sal put that in there?

15 A. Yes. When we were sitting down, he's
16 going through it, and he added stuff that -- that's
17 why when I see check this math -- let me reread it
18 again, please, because I did do some calculations.
19 I think I wrote that. I think I wrote that.

20 Q. So then let's have the reporter please
21 read back the question I asked prior to that, I want
22 you to answer what question, please.

23 (Record read.)

24 A. No, I did not form an opinion. I
25 somehow did some math which doesn't even look

1 correct.

2 Q. Well, but you wrote this in your
3 expert witness report, right?

4 A. Expert witness report which was
5 something that I was continually working on.

6 Q. But you did a calculation --

7 A. I calculated other things in there --
8 I don't even remember the calculation. It doesn't
9 even look like it could be anywhere near correct. I
10 guess if you take the 80/20 rule.

11 Q. So it would be correct then?

12 A. If you -- yeah -- it would be correct
13 what?

14 Q. If you properly applied your theory,
15 then the result of five defective tablets would be
16 correct?

17 A. Yeah. It's a flawed theory.

18 Q. It's a flawed theory, the 80/20 rule?

19 A. No, that therefore five would still
20 remain. This is a statistical approach that five is
21 just an extrapolated number which is I guess
22 20 percent -- 20 plus percent of 20.

23 Q. So but it's a flawed theory?

24 A. The theory, yeah, I would not say that
25 five remained in the market. I have no idea how

1 much would have remained in the market. I have no
2 idea.

3 Q. And in your final report, that fact
4 came out, right, it wasn't in your final report?

5 A. That's correct.

6 Q. Why?

7 A. Because it's -- it shouldn't have been
8 in there in the first place. It's nonsense.

9 Q. It's nonsense? Did you discuss that
10 calculation with Plaintiff's counsel.

11 A. No. No. I don't recall ever, no.

12 Q. Well, Mr. --

13 A. No, no, no. Let me back up. I did
14 not -- can I answer it? No, I did never discuss
15 this with Plaintiff's counsel. No.

16 Q. I guess I should caution you about
17 being so definitive in your testimony since on more
18 than one occasion today, we've learned that some of
19 your fairly definitive testimony has been a little
20 quick in terms of your thinking through it and how
21 accurate it is. So, but you're certain then that
22 you didn't discuss this with Plaintiff's counsel?

23 A. Correct.

24 Q. I'm also looking at, and I'm back in
25 Exhibit 110, the folder of e-mails that you produced

1 earlier today that we marked. And again, I don't
2 have extra copies. I'm looking at an e-mail that is
3 a two page e-mail, and again, it's an e-mail thread
4 with a series of e-mails that relate to scheduling.
5 And it looks as though in the first e-mail,
6 Ms. Johnson asked you and Mr. Romano whether you're
7 available for a call the next day and the date of
8 Ms. Johnson's e-mail is June 8, 2010?

9 A. Okay.

10 Q. In response the following morning --
11 I'm sorry, later that day, you respond and say
12 you're available after 1:00 p.m., and the following
13 morning early, Mr. Romano responds and says he's
14 available until about 3:30 for a call. And then
15 there are further e-mails apparently setting the
16 call for 2 o'clock on June 9, 2010. Do you remember
17 that telephone call?

18 A. No.

19 Q. Any reason to believe that it didn't
20 happen?

21 A. No reason to believe that it didn't
22 happen.

23 Q. All right. That's five days before
24 your report was finalized?

25 A. Okay.

1 Q. Right?

2 A. Yes.

3 Q. I'm sorry, six days. Now I'm not
4 doing math so well. Mr. Romano is still
5 participating in the discussions about the report?

6 A. He's still participating in
7 discussions, yes.

8 Q. Okay. That's not so he can proofread
9 it, is it?

10 MS. CARTER: Objection.

11 A. I don't know what his objectives are.

12 BY MR. ANDERTON:

13 Q. Okay. And the next day, I'm looking
14 at another e-mail dated June 10, 2010, and in the
15 original e-mail -- well, in this e-mail, Ms. Johnson
16 forwards to you as well to the SpyGlass e-mail
17 address, and to Saljromano@aol.com, a copy of a
18 Mylan deposition that "discusses the audits of
19 Actavis and frequency." Now, there's comments in
20 your final report about the frequency of the audits
21 conducted by Mylan on Actavis, aren't there?

22 A. Yes.

23 Q. And that happens to be one of the
24 bullet points in your initial draft that Sal
25 suggested you add to the final version, right?

1 A. I believe that's accurate.

2 Q. So and that is Exhibit 141 that we've
3 talked about here over the last few minutes?

4 A. Yes.

5 Q. So here we are on June 10 and
6 Ms. Johnson is sending to you and Mr. Romano Mylan
7 deposition transcripts for your review and analysis,
8 right?

9 A. Right. Yes.

10 Q. So Mr. Romano is still involved in
11 analyzing records for the purpose of continued
12 preparation of the report?

13 A. No. At that point, Sal basically
14 reviewed nothing.

15 Q. Why is he getting copies of the
16 transcript?

17 A. Out of respect. The fact that he's
18 still part of the project.

19 Q. So he suggests on -- sometime on or
20 about May 26 that you add comments in your report
21 about Mylan's audit practice with respect to
22 Actavis?

23 MS. CARTER: Objection.

24 BY MR. ANDERTON:

25 Q. And two weeks later, you guys receive

1 deposition transcripts from Plaintiff's counsel on
2 just that subject, and Mr. Romano receives them and
3 then that subject ends up in the final version of
4 the report, but he wasn't doing anything?

5 A. He did not do a thing with that,
6 nothing.

7 Q. Just coincidence?

8 A. There's nothing coincidental about it.
9 He did not review those documents. I did. I was
10 the one who looked at them objectively and entered
11 my opinion.

12 Q. Will you get your billing records out,
13 please?

14 A. Yeah. Do you have them or do I have
15 them?

16 Q. I don't have them.

17 A. Okay.

18 Q. Mr. Kenny, will you find your billing
19 records for June?

20 A. May, June.

21 Q. You got them?

22 A. Yes.

23 Q. May I see them very quickly?

24 A. Sure. (Handing).

25 Q. In looking at these, I now realize

1 that you don't provide time or date detail?

2 A. I provide what I provide.

3 Q. So the answer to my question is?

4 A. Well, I have to look at the specifics.
5 I have dates.

6 Q. You don't have -- you have a date
7 range and then a total number of hours with a
8 charge?

9 A. Okay.

10 Q. Right? So there's no way to determine
11 whether Mr. Romano charged any time for reviewing
12 this deposition transcript?

13 A. There would be if you looked at the
14 bills associated with him.

15 Q. Do you have those?

16 A. Yes.

17 Q. May I see those? Are these marked?

18 MS. CARTER: They are all in that
19 same.

20 BY MR. ANDERTON:

21 Q. All in that same folder? Do you have
22 Mr. Romano's bills beyond April and May?

23 A. I believe that should be complete.
24 That's what my wife gave me, Denise.

25 Q. This is not complete. It stops at

1 May 9 for Mr. Romano?

2 A. Then May 9 may have been the last time
3 that he billed.

4 Q. Well, the document I just looked at
5 stops at May 10 actually. So sir, we don't have the
6 time sheet -- according to invoice 1032, there's a
7 time sheet for Mr. Romano for the period May 11 to
8 June 15 and the detail sheets you've just given me
9 don't go past May 10, so that actually fits. Do we
10 have those time sheets?

11 A. I don't have those time sheets.

12 Q. Okay. Will you make a note to
13 yourself to track those down and get those to
14 Plaintiff's counsel?

15 A. Okay. Time sheets for what?

16 Q. Mr. Romano's detailed time sheets for
17 any time after May 10, 2010.

18 A. Post, I'm sorry?

19 Q. Post May 10, 2010.

20 A. Okay.

21 Q. Now, Mr. Kenny, I'm looking at
22 Mr. Romano's time sheets, and on April 10, 2010, he
23 charged one hour for what he characterized a draft
24 report.

25 A. I don't know what that was. What date

1 was it?

2 Q. April 10.

3 A. I don't know.

4 Q. On April 27, he charged an hour -- I'm
5 sorry -- on April 26th, he charged five and a half
6 hours, and the time actually says write draft number
7 one of report?

8 A. Okay. He was doing his own work.

9 Q. Were you also writing parallel drafts?

10 A. Were we writing parallel -- if you
11 could use that term, yes, I guess so.

12 Q. So you wrote a draft and he wrote a
13 draft?

14 A. He made some notes and gave them to
15 me.

16 Q. This says write draft number one of
17 report?

18 A. Yes.

19 Q. Is that making notes?

20 A. Yes, it was very cryptic of which he,
21 I believe, cut and pasted them into my document when
22 I was there.

23 Q. Do you have the time detail sheets for
24 your time for this period?

25 A. I don't know. You have what I have.

1 Q. Well, what I don't have is any detail
2 for. You see how this has the description of
3 services for Mr. Romano? I don't have any of those
4 for you. I have only invoices.

5 A. I should have those. I have them.

6 Q. Do you have those?

7 A. If they are not there, no, I don't
8 have them with me.

9 Q. Actually, I misspoke. I do have some
10 of yours. My apologies, Mr. Kenny. I didn't look
11 at it closely enough. So I'm looking at your time
12 sheets now, I do have them, detailed time sheets.
13 And I start with the date of February 26, which is
14 the earliest entry which is consistent with the fact
15 that you said earlier it was around the 23rd or
16 fourth when you first got documents from Plaintiff's
17 counsel. And as I look at your time entries all the
18 way through the end of April, I don't see any
19 drafting by you. Is that accurate?

20 A. From when to when?

21 Q. From February through April 24, 2010.
22 I see no drafting by you?

23 A. No. I did drafting. I did drafting
24 of the tables. I started on the tables.

25 Q. While Mr. Romano was drafting the

1 report.

2 A. He was drafting -- something, I'm not
3 sure what he was drafting.

4 Q. Well, so on April -- well, he spent
5 five and a half hours on it. That sounds like a
6 little more than notes?

7 A. Well, he drafted something.

8 Q. You were charging plaintiff's counsel
9 \$430 an hour?

10 A. He was charging them and he was
11 working on the report.

12 Q. \$430 an hour?

13 A. Yes.

14 Q. So five and a half hours is \$2300 or
15 so?

16 A. Yes.

17 Q. Does that sound about right, maybe
18 even a little more than that?

19 A. Yes.

20 Q. And he told Plaintiff's counsel that
21 he was writing a draft of the report, and that
22 that's what they were paying him \$2300 for. You're
23 now saying he wasn't doing that?

24 A. I don't know what he was doing.

25 MS. CARTER: Objection.

1 A. He gave my wife the bills, and they're
2 sent out.

3 BY MR. ANDERTON:

4 Q. And he gave you the draft of the
5 report for you to review as well, right?

6 A. He gave me the draft of a report, no,
7 we sat down to review that report. We -- we sat
8 down to review what he had done.

9 Q. Okay. The next day, he charged
10 another hour and a half for what he characterized as
11 work on report. Two days after that, he charged
12 three hours, again, work on report. The following
13 week, May 4, he charged a half hour, work on report.
14 That's ten and a half hours that he's characterized
15 as drafting and working report. You say he's not
16 doing any drafting?

17 A. I'm not sure what he's doing. I know
18 he was at one point going to try to do the footnotes
19 or the references.

20 Q. So the first draft that you produced
21 indicated that he was drafting and going to testify.
22 His time records are consistent with that?

23 A. Uh-huh.

24 Q. And you somehow are begging off that
25 and saying he wasn't doing that actually?

1 MS. CARTER: Objection.

2 A. I don't know what he did. I don't
3 know what he was working on.

4 BY MR. ANDERTON:

5 Q. Well, we know exactly what he did. We
6 have a draft report that indicates he was -- it was
7 drafted by him in April and early May, right?

8 MS. CARTER: Objection.

9 BY MR. ANDERTON:

10 Q. Is that right?

11 A. Yes, that's what the records state.

12 Q. Okay. You don't have any reason to
13 believe these records are falsified, do you?

14 A. No. I have no reason to believe that.

15 Q. I would be very curious to see those
16 additional time sheets from Mr. Romano, and I don't
17 think yours are in here as well, okay?

18 A. Yeah.

19 Q. Past May.

20 A. I'm sorry. What am I looking for?

21 Q. Your detailed time sheets for time
22 beyond May 10?

23 A. They are not there?

24 Q. Neither of your detailed time sheets
25 are here. The latest entry for either one of you is

1 May 10. You'll track those down?

2 A. Absolutely.

3 Q. Thank you very much.

4 In earlier deposition on June 29, you
5 talked about process validation, and Mr. Moriarty
6 asked you questions about whether you looked at
7 process validation. Do you remember that testimony?

8 A. Yes. Yes.

9 Q. As somebody who is evaluating
10 whether -- or at least the likelihood, of whether
11 adulterated product was produced, process validation
12 is a pretty critical document, isn't it?

13 A. It's a portion of that, yes.

14 Q. So it's a very important document,
15 isn't it?

16 A. Yes.

17 Q. In fact, it's kind of the jumping off
18 point for the whole analysis, isn't it?

19 A. No, I wouldn't call it that. It's
20 like everything else, it's an important step in the
21 development process, in the commercialization
22 process.

23 Q. If you were hired by a pharmaceutical
24 manufacturer today and they said, Mr. Kenny, we'd
25 like you to evaluate whether we have produced any of

1 product X that is adulterated, could you do that
2 analysis without looking at the process validation?

3 A. Could I do it? I could if I found
4 instances where adulteration occurred, but I don't
5 need that because I could do it by exception. If I
6 saw falsified results, if I saw, let's say results
7 in a record that are not specification when in fact
8 they accepted it. It doesn't meet specification.
9 So I don't need to look at validation in order to
10 find exceptions to determine whether it violates
11 GMP.

12 Q. Would you ask to see the process
13 validation?

14 A. Yes.

15 Q. Back to a point I made a moment ago,
16 the process validation is significant because it's
17 somewhat of a foundation for whether you have
18 developed and created a process that is capable of
19 consistently manufacturing product within
20 specification, right?

21 A. I wouldn't phrase it that way, but
22 it's very important as part of the development
23 process and the commercialization process.

24 Q. Okay. In fact, the commercialization
25 process cannot go forward without a validated

1 process; is that right?

2 A. That is correct.

3 Q. If the FDA came in and did an audit
4 and determined that your process wasn't validated,
5 they would do whatever they could to make you stop
6 making that product almost immediately, wouldn't
7 they?

8 A. Correct.

9 Q. But you didn't look at the process
10 validations for DIGITEK in this litigation, did you?

11 A. I did not go into detail on those.

12 Q. You saw the .5 milligram process
13 validation, but did not ask for the other process
14 validations, did you?

15 A. I apparently did not ask for them,
16 yes. I really don't recall, quite honestly.

17 Q. Do you have any reason to believe that
18 you actually asked for the additional process
19 validations?

20 A. I don't recall, honestly.

21 Q. Well --

22 A. But your question is again.

23 Q. Do you have any reason to believe that
24 you did asked for them?

25 A. No recollection that I asked for them.

1 Q. Okay. What did you ask, for
2 additional documents? I mean, we saw earlier that
3 you asked for batch records and didn't get them?

4 A. Uh-huh.

5 Q. Do you remember asking for and getting
6 anything other than the FDA documents that
7 plaintiffs thought were so important?

8 MS. CARTER: Objection.

9 A. The documents that were available to
10 me were on Crivella, and I was able to do a search
11 and try to find a document. If I couldn't find it,
12 it wasn't there. That was the database. So it
13 would be futile to ask for a document that didn't
14 exist because it was not there.

15 BY MR. ANDERTON:

16 Q. Do you remember the last time that you
17 were deposed giving testimony about an unsigned
18 memo?

19 A. There were several unsigned documents,
20 but yeah.

21 Q. Okay. I'm handing you a document that
22 has previously been marked as Plaintiff's Exhibit
23 317. Take a moment to look at that document.

24 A. Sure.

25 Q. Have you seen that document before?

1 A. Yes, I saw it as an unsigned document.

2 Q. As an unsigned document?

3 A. That's correct.

4 Q. And when you were deposed in June, you
5 testified about the unsigned document, didn't you?

6 A. Yes, I did.

7 Q. And you spoke pretty harshly about it,
8 didn't you?

9 A. I wouldn't use the term "harshly," I
10 made comment to it.

11 Q. Well, you said, and this is from page
12 277 of your prior deposition, "because the value,
13 even if it were a very logical explanation," that
14 it's not signed, is what you're referring to, "the
15 value of it is nill. It is a gross violation of
16 GMP, and how that document could have been created
17 and distributed and how anybody would have received
18 it and not kicked it back to the original person to
19 make sure it wasn't signed or dated is beyond me.
20 It's a total -- talk about a breakdown. This is a
21 significant breakdown."

22 That's a pretty harsh characterization,
23 isn't it?

24 A. Yes.

25 Q. Did you ever consider that the

1 unsigned version might be a draft?

2 A. Did I consider that, yes, I suppose I
3 did consider it.

4 Q. What did you do to satisfy yourself if
5 you considered it that it in fact wasn't a draft?

6 A. I did do anything in addition.

7 Q. So you're more than happy to supply
8 that scathing testimony about the GMP practices of
9 Actavis when you yourself didn't feel it was
10 necessary to do anything to satisfy your own logical
11 inquiry about whether that was the final version of
12 that document?

13 MS. CARTER: Objection.

14 A. I assumed that it was there. It was
15 the final document, the original was asked for, and
16 it did not exist. That was my assumption. I didn't
17 go and search to see if -- I don't know how I could
18 search for a document that -- a second document that
19 was signed versus one that was unsigned.

20 BY MR. ANDERTON:

21 Q. Do you know the nature of document
22 productions in litigations this large?

23 A. No.

24 Q. You don't know anything about how many
25 documents or whether drafts are produced or anything

1 like that?

2 A. No.

3 Q. You see the sticker on that document,
4 the 317, do you see the date on it?

5 A. Yes.

6 Q. What is it?

7 A. Well, it says underneath the Exhibit
8 number, 51410.

9 Q. That means that document was used as
10 an exhibit by plaintiff's counsel in a deposition on
11 May 14, 2010, a month before you finalized your
12 report, and a month and a half before you testified.
13 It was available to you, readily available. In
14 fact, plaintiffs had used it as an exhibit. You
15 didn't feel it was even worth asking them whether
16 that was a draft?

17 A. It wasn't a matter of asking them. I
18 saw the document, I assumed that that naturally was
19 the single document. I made an assumption.

20 Q. An obviously incorrect assumption?

21 MS. CARTER: Objection.

22 A. It turned out to be incorrect that it
23 did exist.

24 MR. ANDERTON: I want to consult with
25 Mr. Kaplan for a moment. We're going to go

1 out and take a break for a moment. I may be
2 done.

3 THE VIDEOGRAPHER: We're off the
4 record. The time is 6:10.

5 (Recess taken.)

6 THE VIDEOGRAPHER: I'm going to start
7 up in a minute. We're back on the record.
8 The time is 6:16.

9 MR. ANDERTON: I have no further
10 questions at this time.

11 MS. CARTER: I have just literally
12 three questions.

13 EXAMINATION BY MS. CARTER:

14 Q. Your final report which is Exhibit 48,
15 I believe somewhere around here, you agree with all
16 of the opinions in this report?

17 A. I absolutely do.

18 Q. You stand by all the opinions in the
19 report?

20 A. I stand by them all.

21 Q. And these opinions you believe are
22 within your area of expertise?

23 A. Yes, I do.

24 And can I make a statement that this
25 report was not signed I have to retract because it

1 indeed was signed. It doesn't mean that it's a
2 quality document, but indeed it was signed.

3 MR. ANDERTON: By "this," you're
4 talking about what we discussed as having
5 previously been marked as Plaintiff's
6 Exhibit 137?

7 THE WITNESS: Yes.

8 MS. CARTER: That's all I have.

9 MR. ANDERTON: No further questions.

10 THE VIDEOGRAPHER: This is the end of
11 the deposition of Mark Kenny. Today's date
12 is February 16, 2011. The time is 6:17.
13 We're off the record.

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C E R T I F I C A T E

STATE OF NEW YORK)

: Ss

COUNTY OF DUTCHESS)

I, Jane Watson, a Reporter and Notary
Public within and for the State of New York
do hereby certify:

That MARK KENNY, the witness whose
deposition is hereinbefore set forth, was duly
sworn by me and that such deposition is a true
record of the testimony given by such witness.

I further certify that I am not related
to any of the parties to this action by blood
or marriage, and that I am in no way
interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my
hand this 21st day of February, 2011.

JANE D. WATSON